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(54) Title: CATHETERS WITH IMPROVED TRANSITION

(57) Abstract: The present invention is directed to a balloon catheter, such as a dilatation catheter and a stent delivery catheter with improved stiffness transition and specifically with no sudden changes in stiffness along the catheter length. The balloon catheters of the present invention may be used alone or be mounted with a stent in. The balloon catheters of the present invention may be used in peripheral, coronary, or neurovascular applications. The present catheter has more than one portion with different bending stiffness values, each portion comprising components that gradually transition the bending stiffness of that portion to an adjacent portion, thus reducing the differential in bending stiffness in moving from one region to another, when the catheter is used alone or in combination with a stent in a stent delivery system.

CATHETERS WITH IMPROVED TRANSITION

FIELD OF INVENTION

The invention relates to the field of intravascular delivery systems, and more particularly to balloon catheters for stent delivery in the intracranial vasculature, referred to herein as neurovasculature.

BACKGROUND OF THE INVENTION

In neurovascular angioplasty procedures a guiding catheter is advanced until the distal tip of the guiding catheter is just proximal to the origin of the intracranial arteries that lead to the target vascular site. A guidewire, positioned within an inner lumen of a dilatation catheter, is first advanced out of the distal end of the guiding catheter into the patient's intracranial vasculature until the distal end of the guidewire crosses a lesion to be dilated. Then the dilatation catheter, having an inflatable balloon on the distal portion thereof, is advanced into the patient's intracranial vasculature over the previously introduced guidewire until the balloon of the dilatation catheter is properly positioned across the lesion. Once properly positioned, the dilatation balloon is inflated with liquid saline or radiopaque contrast one or more times to a predetermined size at relatively high pressures (e.g. at least about 4-6 atmospheres) so that the lesion is dilated to restore vessel patency. However, damage to the vessel wall at and around the lesion can result from the expansion of the balloon against the vessel wall. After the balloon is finally deflated, blood flow resumes through the dilated vessel and the dilatation catheter can be removed therefrom.

In such neurological angioplasty procedures, there may be restenosis of the lesion due to acute or sub-acute (chronic)

complications, such as vessel recoil, lesion dissection, intimal hyperplasia, or other factors. The resulting restenosis may in turn necessitate either another angioplasty procedure, or some other method of repairing or strengthening the dilated area. In similar coronary angioplasty, the restenosis rate is reduced and the dilated area is strengthened by implanting an intravascular prosthesis, generally called a stent, inside the artery at the site of the lesion. However, currently, this treatment modality is not available in neurovascular applications due primarily due to the inability to access the distal, highly tortuous anatomy of the neurovascular system with conventional stent delivery systems. Further details of stents and stent delivery systems for PTCA procedures can be found in U.S. Pat. Nos. 5,507,768 (Lau *et al.*), 5,458,615 (Klemm et al.), and 5, 514,154 (Lau et al.), which are incorporated herein by reference in their entireties. Commonly used coronary stent delivery systems are too inflexible to track through the neuro anatomy. Furthermore, they tend to kink when bent into tight radius curves.

Therefore, what has been needed is a catheter and stent delivery system suitable for use in neurovascular applications. The present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

The present invention is directed to a balloon catheter, such as a dilatation catheter and a stent delivery catheter with improved stiffness transition and specifically with no sudden changes in stiffness along the catheter length. In the balloon catheters of the invention alone or mounted with a stent, whether used for peripheral, coronary, or neurovascular applications, is important to reduce the significant bending stiffness changes (herein referred to as bending stiffness discontinuity) present

along the length of the catheter. It should also be appreciated that although in describing features of the present invention, the features are directed primarily to a neurovascular stent delivery system, the invention is also applicable to coronary and peripheral stent delivery systems, as well as dilatation catheters for peripheral, neurological, coronary, and similar applications.

Having smooth transitions from one region to another along the length of the catheter, in particular, when a stent is located on the catheter, is of particular importance in neurovascular applications. The major design challenge for a Neurovascular Stent Delivery System (NSDS), in particular, has been in improving the ability to access the distal, highly tortuous anatomy of the neurovascular system. In order to meet this challenge, the present invention provides for a catheter and stent delivery system optimized for flexibility and kink-resistance. Improved flexibility allows the device to turn tight corners along the vasculature without applying large forces against the wall of the vessels, thus minimizing the surface friction between the catheter and the vessel. This allows more distal access, particularly in tortuous neurovascular anatomy.

The optimization of flexibility for the neurovascular stent delivery system may aggravate the kinking dynamic, as for example, bending stiffness discontinuities can be more pronounced as some softer catheter members are more likely to kink than stiffer members. Kinking of the catheter is also a common constraint to distal access. The kink creates a hinge point in the catheter so that the catheter can no longer navigate tight radius turns in the vasculature. Kinks often occur at the interface of two regions along the device having substantially different bending stiffness (i.e., have a discontinuity in the bending stiffness). Examples of such interfaces, include, but are

not limited to: the proximal and distal ends of a stent disposed on a catheter, and areas adjacent the balloon seals and marker bands.

The stent delivery system of the present invention, in particular as adapted for neurovascular applications, has been optimized for flexibility and kink resistance. The kink resistance has been achieved by minimizing the differential in bending stiffness at the troublesome regions. The present invention includes various embodiments for minimizing the bending stiffness differential as well as increasing the overall flexibility of the catheter, including but not limited to one or more of the following: (1) the lengthening and softening of the catheter tip and the distal balloon seal while maintaining a low profile, (2) crimping the ends of the stent onto the marker bands, (3) locating stiffening sleeves on the inner member on or near the ends of the stent, (4) using a variable stiffness inner member, and (5) providing variable stiffness sheath on the catheter particularly over the stent; in order to reduce the stiffness differential among adjacent portions along the catheter.

In the practice of the present invention, the areas of low bending stiffness located immediately before or after an area of higher bending stiffness may be "built up" in stiffness to gradually transition the stiffness of that portion to an adjacent portion of higher value, thus providing a relatively smooth transition from one region to another.

In other words, the present catheter has more than one portion with different stiffness values, each portion comprising of components that gradually transition the stiffness of that portion to an adjacent portion, thus reducing the differential in bending stiffness in moving from one region to another, when the catheter is used alone or in combination with a stent in a stent delivery system.

The stent delivery system of the present invention includes a catheter having an elongated shaft with proximal and distal ends and an inner lumen extending therein. The system further includes an enlargeable member mounted on a distal shaft section proximal to the distal end which is configured for supporting a deployable prosthetic device on a receiving portion thereon. The enlargeable member has an interior in fluid communication with the inner lumen. Furthermore, a tubular member extends through the interior of the enlargeable member.

In one embodiment, the stent delivery system further includes proximal and distal radiopaque markers disposed on a portion of the tubular member extending within the interior of the enlargeable member. Preferably, a portion of each marker is within and a portion is outside the receiving portion of the enlargeable member. Optionally, the catheter system may further include at least one jacket disposed on a portion of the tubular member extending within the interior of the enlargeable member. The jacket overlays, at least in part, at least one of the proximal and distal markers. The jacket, preferably, extends, at least in part, outside the receiving portion of the enlargeable member. The jacket may include an outer and an inner layer. A portion of the inner layer is adjacent the tubular member extending through the interior of the enlargeable member. The system may further include at least one outer jacket formed of a material relatively stiffer than the jacket material. The outer jacket butts up to at least one of the proximal and distal markers. The at least one outer jacket may be, at least partially, overlaid with the jacket.

Alternatively the stent delivery system further includes more than one portion with different stiffness values. Each portion comprises of components that gradually transition the stiffness of that

portion to an adjacent portion. Preferably, the stiffness ratio between any two adjacent portions is at least f, more preferably from about 0.3 to about 0.7, and most preferably, at least 0.7. Alternatively, the system further include an outer tubular member and an inner tubular member. The outer tubular member may include more than one section, the sections having a decrease in stiffness in the distal direction. The inner member may include more than one section, the sections having a decrease in stiffness in the distal direction. Alternatively, the stiffness of a portion of the inner tubular member may be built up to more smoothly match the stiffness of an adjacent portion of higher stiffness. Alternatively, the system may further include proximal and distal radiopaque markers disposed on a portion of the tubular member extending within the interior of the enlargeable member. Alternatively, the at least one portion of the tubular member extending within the interior of the enlargeable member includes a tubular member with an imbedded coil for providing a gradual transition in stiffness of that portion to the enlargeable member receiving portion upon receiving the deployable member thereon. Alternatively, the system may further include a retractable sheath disposed over at least a portion of the catheter shaft for covering the deployable member once the deployable member is mounted on the catheter. The sheath, preferably, has a variable stiffness to minimize kinking of the catheter near or at proximal and distal ends of the deployable member.

In another embodiment, the stent delivery system further includes at least one radiopaque segment having proximal and distal ends. The at least one radiopaque segment is disposed, at least in part, within the enlargeable member. The catheter shaft has a sufficiently gradual change in stiffness from a point proximal to the

proximal end of the radiopaque segment to at least the proximal end of the radiopaque segment to minimize kinking of the catheter upon application of force during a medical procedure. Additionally, the enlargeable member includes a deployable member receiving portion having proximal and distal receiving ends with the at least one radiopaque segment located longitudinally within and outside the deployable receiving portion. Alternatively, the radiopaque segment has a conical shape with a conicity away from the receiving portion. Alternatively, the radiopaque segment is integral with the tubular member extending through the enlargeable member.

Alternatively, the stent delivery system further includes an outer tubular member and an inner tubular member with a distal inner member having a portion extending through the enlargeable member. The extending portion of the distal inner member includes at least one tubular sleeve disposed about and attached to the distal inner member. The at least one tubular sleeve has sufficient stiffness to provide a relatively smooth stiffness transition from a point along the catheter shaft proximal to a proximal edge of the at least one tubular sleeve to a point along the catheter shaft distal to a distal edge of the at least one tubular sleeve. Additionally, the proximal tubular sleeve is extended into a distal end of the outer tubular member forming a proximal overlap region to minimize proximal transition kinking. Optionally, a portion of the distal end of the outer tubular member is extended into the proximal section of the enlargeable member and the proximal overlap is located within the extended portion.

In another embodiment, the stent delivery system further includes an outer tubular member having a distal edge and an inner tubular member. The distal edge of the outer tubular member extends distally to a point being at the same transverse location or proximal to

a proximal end of the receiving portion. Optionally, the distal edge of the outer tubular member may extend distal to the proximal end of the receiving portion.

In another embodiment, the stent delivery system the enlargeable member forms proximal and distal fluid-tight seals with the catheter shaft at the enlargeable member proximal end and distal ends, respectively. The distal seal of the enlargeable member may have perforations or grooves thereon to provide a gradual stiffness reduction in the distal direction.

In another embodiment, the stent delivery system further includes a catheter tip at the shaft distal end and includes an atraumatic distal tip having a distal end. The tubular member extending through the enlargeable member has a distal end which is butt-joined to a proximal end of the atraumatic distal tip. An outer layer member may be butt-jointed or lap-jointed to the distal end of the enlargeable member at a point proximal to the tubular member distal end. The outer layer extends distally to a point proximal to the distal end of the atraumatic distal tip.

The balloon catheter of the present invention includes a catheter having an elongated shaft with proximal and distal ends and an inner lumen extending therein. The system further includes an enlargeable member mounted on a distal shaft section proximal to the distal end. The enlargeable member has an interior in fluid communication with the inner lumen. Furthermore, a tubular member extends through the interior of the enlargeable member.

In one embodiment, the balloon catheter further includes proximal and distal radiopaque markers disposed on a portion of the tubular member extending within the interior of the enlargeable member. Optionally, the balloon catheter may further include at least

one jacket disposed on a portion of the tubular member extending within the interior of the enlargeable member. The at least one jacket overlays, at least in part, at least one of the proximal and distal markers.

Alternatively the balloon catheter further includes more than one portion with different stiffness values. Each portion comprises of components that gradually transition the stiffness of that portion to an adjacent portion. Preferably, the stiffness ratio between any two adjacent portions is at least 0.3, more preferably from about 0.3 to about 0.7, and most preferably, at least 0.7. Alternatively, the balloon catheter further include an outer tubular member and an inner tubular member. The outer tubular member may include more than one section, the sections having a decrease in stiffness in the distal direction. The inner member may include more than one section, the sections having a decrease in stiffness in the distal direction. Alternatively, the stiffness of portion of the inner tubular member may be built up to more smoothly match the stiffness of an adjacent portion being of higher stiffness. Alternatively, the balloon catheter may further include proximal and distal radiopaque markers disposed on a portion of the tubular member extending within the interior of the enlargeable member. Alternatively, the at least one portion of the tubular member extending within the interior of the enlargeable member includes a tubular member with an imbedded coil for providing a gradual transition in stiffness of that portion to an adjacent portion of higher stiffness. Alternatively, the balloon catheter may further include a sheath disposed over at least a portion of the enlargeable member. The sheath, preferably, has a variable stiffness to minimize kinking of the catheter near or at the enlargeable member.

In another embodiment, the balloon catheter further includes at least one radiopaque segment having proximal and distal ends. The at least one radiopaque segment is disposed, at least in part, within the enlargeable member. The catheter shaft has a sufficiently gradual change in stiffness from a point proximal to the proximal end of the radiopaque segment to at least the proximal end of the radiopaque segment to minimize kinking of the catheter upon application of force during a medical procedure. Additionally, at least one radiopaque segment may be located longitudinally within the interior of the enlargeable member. Alternatively, the radiopaque segment has a conical shape with a conicity away from the intermediate section of the enlargeable member. Alternatively, the radiopaque segment is integral with the tubular member extending through the enlargeable member.

Alternatively, the balloon catheter further includes an outer tubular member and an inner tubular member with a distal inner member having a portion extending through the enlargeable member. The extending portion of the distal inner member includes at least one tubular sleeve disposed about and attached to the distal inner member. The at least one tubular sleeve has sufficient stiffness to provide a relatively smooth stiffness transition from a point along the catheter shaft proximal to a proximal edge of the at least one tubular sleeve to a point along the catheter shaft distal to a distal edge of the at least one tubular sleeve. Additionally, the proximal tubular sleeve is extended into a distal end of the outer tubular member forming a proximal overlap region to minimize proximal transition kinking. Optionally, a portion of the distal end of the outer tubular member is extended into the proximal section of the enlargeable member and the proximal overlap is located within the extended portion.

In another embodiment, the balloon includes proximal and distal sections with an intermediate section therebetween. The balloon catheter further includes an outer tubular member having a distal edge and an inner tubular member. The distal edge of the outer tubular member extends distally within the intermediate portion of the enlargeable member. Optionally, the distal edge of the outer tubular member may extend distal to a proximal end of the intermediate section.

In another embodiment, the enlargeable member of the balloon catheter forms proximal and distal fluid-tight seals with the catheter shaft at the enlargeable member proximal end and distal ends, respectively. The distal seal of the enlargeable member may have perforations or grooves thereon to provide a gradual stiffness reduction in the distal direction.

In another embodiment, the balloon catheter further includes a catheter tip at the shaft distal end and includes an atraumatic distal tip having a distal end. The tubular member extending through the enlargeable member has a distal end which is butt-joined to a proximal end of the atraumatic distal tip. An outer layer member may be butt-joined to the distal end of the enlargeable member at a point proximal to the tubular member distal end. The outer layer extends distally to a point proximal to the distal end of the atraumatic distal tip.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a longitudinal cross sectional view of a stent delivery system embodying features of the invention.

Fig. 2 is a transverse cross sectional view of the delivery system of Fig. 1 taken along line 2-2.

Fig. 3 is a transverse cross sectional view of the delivery system of Fig. 1 taken along line 3-3.

Fig. 4 is a longitudinal cross sectional view of the system of Fig. 1 showing an inflatable member in the inflated condition.

Fig. 5(A) is a longitudinal cross sectional view of an alternative embodiment of a delivery system having an outer and inner tubular member with multiple sections.

Fig. 5(B) is longitudinal view of an alternative embodiment of the delivery system of Fig. 5(A) having different stiffness ratios along the length of the catheter..

Fig. 6(A) is a longitudinal cross sectional view, in part, of an alternative embodiment of a delivery system having an outer and inner tubular member with the inner tubular member having at least one tubular sleeve disposed about and attached to a portion thereof.

Fig. 6(B) is an alternative embodiment of the system of Fig. 6(A) having at least one radiopaque marker disposed on the inner tubular member and in contact with the at least one tubular sleeve.

Fig. 7 is an alternative embodiment of the system in Fig. 6(B) showing a proximal end of a proximal tubular sleeve extended into a distal end of the outer tubular member and forming a proximal overlap.

Fig. 8 is a longitudinal cross sectional view, in part, of an alternative embodiment of a delivery system having an outer and an inner tubular member with a distal end of the outer tubular member extended into an inflatable member intermediate area.

Fig. 9 is a longitudinal cross sectional view, in part, of an alternative embodiment of a delivery system having a proximal and a distal radiopaque marker positioned on an inner member with the proximal marker extending on both sides of a proximal edge of a stent and the distal marker extending on both sides of a distal edge of the

stent in addition to having a flexible jacket in contact with each marker.

Figs. 10 (A) through 10 (E) are longitudinal cross sectional views, in part, of alternative embodiments of Fig. 9 showing the markers and the one or more jackets.

Fig. 11 is a longitudinal cross sectional view, in part, of an alternative embodiment of a delivery system of Fig. 9 with the proximal and distal jackets extending, respectively, proximal and distal to the inflatable member intermediate section.

Fig. 12 is a longitudinal cross sectional view, in part, of an alternative embodiment of a delivery system having a conical shaped marker disposed on an inner member.

Figs. 13(A) through 13(C) are cross sectional views, in part, of alternative embodiments of a delivery system having perforations or grooves on a catheter tip.

Fig. 14 is cross sectional view, in part, of alternative embodiment of the delivery system of Figs. 13 (A) through 13(C) showing a tapered distal seal.

Fig. 15(A) is a cross sectional view, in part, of alternative embodiment of a delivery system having a catheter tip including an atraumatic tip and outer layer member.

Fig. 15(B) is cross sectional view, in part, of the catheter tip of Fig. 15(A) after a sealing process, the tip being tapered.

Fig. 16 is a longitudinal cross sectional view, in part, of an alternative embodiment of a delivery system having an inner tubular member comprising at least in part of a tubular member with an imbedded coil, the inner tubular member having variable stiffness along its length.

Fig. 17 is longitudinal cross sectional view, in part, of an alternative embodiment of a delivery system having a variable stiffness sheath disposed over at least a part of the stent.

Fig. 18 is a cross section view of an alternative embodiment of the sheath in Fig. 17 having an imbedded coil.

Fig. 19 is a diagrammatic illustration of a force versus distance curve showing a smoother stiffness transition along the catheter of the present invention compared to others.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 illustrates a balloon catheter 10 embodying features of the invention. The balloon catheter 10 of the invention generally includes an elongated catheter shaft 13 having a proximal section 16 and a distal section 19 with a distal end 22 and a distal tip 25, an enlargeable member such as an inflatable balloon 28 on the distal section 19 of the catheter shaft 13, and an adapter 31 mounted on the proximal section 16 of the catheter shaft 13. In the embodiment illustrated in Fig. 1, the balloon catheter 10 has a stent 34 mounted on the balloon 28 to form a stent delivery catheter system 37. In Fig. 1, the catheter system 37 is illustrated within a patient's body lumen 40 prior to expansion of the balloon 28, with the balloon 28 and stent 34 in a low profile, unexpanded state for advancement within the patient.

In the embodiment illustrated in Fig. 1, the catheter shaft 13 has an outer tubular member 43 and an inner tubular member 46 disposed within the outer tubular member 43 and defining, with the outer tubular member, an inflation lumen 49. The inflation lumen 49 is in fluid communication with an interior chamber 52 of the inflatable balloon 28. The inner tubular member 46 has an inner lumen 55

extending therein configured to slidably receive a guidewire 58 suitable for advancement through a patient's vasculature. A distal extremity 61 of the inflatable balloon 28 is sealingly secured to a distal extremity 64 of the inner tubular member 46 to form a distal seal 67 at distal junction 70 and a proximal extremity 73 of the balloon 28 is sealingly secured to a distal extremity 76 of the outer tubular member 43 to form a proximal seal 79 at a proximal junction 82. Figs. 2 and 3 illustrate transverse cross sectional view of the catheter 10 shown in Fig. 1, taken along lines 2-2 and 3-3, respectively.

As best illustrated in Fig. 4, the balloon 28 has an intermediate section 85 located thereon, preferably centrally, with proximal and distal intermediate ends, 88 and 91. The intermediate section 85 includes a stent-receiving portion 94 with proximal and distal receiving ends, 97 and 100, respectively, for receiving a stent thereon, and proximal and distal intermediate portions 103 and 106, adjacent the proximal and distal receiving ends, 97 and 100, respectively. However, it is possible for all or part of the stent-receiving portion 94 to coincide with the intermediate section 85. The balloon 28 further includes a proximal tapered area 109 adjacent the proximal end 88 of the intermediate section 85 and a distal tapered area 112 adjacent the distal end 91 of the intermediate section 85. The proximal and distal tapered areas 109 and 112 taper down to a proximal and distal shaft 115 and 118, respectively. The proximal balloon shaft 115 and the distal balloon shaft 118 are secured to the outer tubular member 43 and the inner tubular member 46, respectively, using a variety of suitable means such as adhesive and fusion bonding.

In operation, when the stent 34 is mounted on the stent-receiving portion 94 of the balloon 28, the proximal and distal intermediate portions, 103 and 106, are first expanded at a first

pressure, with the stent-receiving portion 94 still in a substantially in an uninflated low profile configuration. The proximal and distal intermediate portions, 103 and 106, expand together at the first pressure to an inflated outer diameter which is greater than the uninflated outer diameter of stent-receiving portion 94 and the stent 34 thereon. As best illustrated in Fig. 4, when the inflation pressure is increased to the deployment pressure of the stent 34, the stent-receiving portion 94 expands against the vessel wall to expand the stent 34 thereon or to dilate a stenosis.

Referring back to Fig. 1, the catheter shaft 13 will generally have the following dimensions. The length of the catheter shaft 13 may be from about 75 cm to about 175 cm, and in the neurovascular application it is typically about 160 cm. The outer tubular member 43 has a length of approximating that of the shaft 13 with an outer diameter (OD) of about 0.030 inches (in) to about 0.060 in, and an inner diameter (ID) of about 0.025 to about 0.050 in. The inner tubular member 46 has a length of about 160 cm, an OD of about 0.018 to about 0.035 in and an ID of about 0.014 to about 0.020 in. The outer and inner tubular members, 43 and 46, may taper in the distal direction to a smaller OD or ID.

The catheter includes more than one portion with different stiffness values, one or more portions comprising of components that gradually transition the stiffness of that portion to an adjacent portion. Preferably, the stiffness of a relatively distal portion is less than the stiffness of a portion immediately proximal to that relatively distal portion. It should however be appreciated that in some portions of the catheter the stiffness of a first portion may be built up, with additional elements or by modifying existing elements, to about the stiffness of a second higher stiffness portion adjacent the first portion in order

effectuate a smoother stiffness transition from the first portion to the adjacent second portion of initially higher stiffness. This, for example, may occur with respect to the stent receiving portion and adjacent areas on either or both its proximal and distal sides wherein the stiffness of the inner member proximal to the proximal receiving end is built up to about the stiffness of the receiving portion with a stent mounted thereon, with building down of the stiffness in moving from the distal receiving end toward the distal end of the catheter. In particular, when the catheter is used as a stent delivery catheter, the various portions of the catheter shaft are designed to allow for a smooth transition in stiffness between adjacent portions when a stent is mounted on the catheter.

In a preferred embodiment the stiffness ratio between any two adjacent portions is at least about 0.3, more preferably, between about 0.3 to about 0.7, and most preferably, greater than about 0.7. Additionally, the illustrated marker positions, as for example illustrated in Fig. 1, are representative of one embodiment and although markers 193 may be shown in any of the Figures, such as Fig. 1, the location of the markers are not limited to that illustrated.

In order to achieve the stent delivery catheter system 37 of the present invention having improved stiffness transition profile, the catheter 10 may further include one or more of the features further described below.

In one embodiment, features of which are illustrated in Fig. 5(A), the outer tubular member 43 includes multiple sections, such as the proximal outer member 121, the intermediate outer member 124, and the distal outer member 127, the sections decreasing in stiffness in the distal direction. In the embodiment featured in Fig. 5(A), the intermediate outer member 124 has a proximal end 130 and a distal

end 133, with the distal end 133 being necked down, enabling the intermediate outer member 124 to join, at its distal end 133 with a proximal end 136 of the distal outer member 127. Similarly, the proximal outer member 121 at a distal end 139 is necked down, enabling the proximal outer member 121 to join, at its distal end 139 with the proximal end 130 of the intermediate outer member 124.

The multiple stage (sectioned) outer tubular member 43 with decreasing relative bending stiffness in the distal direction improves the compressive loading efficiency of the catheter 10 while maximizing the flexibility of the catheter 10 at its distal section 19. The relative stiffness of the proximal outer member 121 improves push transmission. The intermediate outer member 124 is of such longitudinal dimension that the distal end 133 of the intermediate outer member 124 does not enter the region of greatest tortuosity within the intracranial vasculature. The moderate flexibility of the intermediate outer member 124 maintains push efficiency while lessening the likelihood of vessel trauma. The distal outer member 127 is relatively flexible and is of sufficient longitudinal dimension to negotiate the stent 34 through highly tortuous anatomy. Additionally, the gradual change in the stiffness minimizes the likelihood of kinking.

In a preferred embodiment, the proximal, intermediate, and distal outer member sections 121, 124, and 127, will be formed of material having flexural modulus stiffness values in a range from about 50 to about 200×10^4 lb/in^2, from about 5 to about 6 $\times 10^4$ lb/in^2, and from about 1.3 to about 1.7 $\times 10^4$ lb/in^2, respectively. Preferred material for forming sections 121, 122, and 127 include, respectively, polyetheretherketone (PEEK), polyetherimide (PEI) such as those sold commercially under the ULTEM designation by General Electric, and stainless steel; polyether block amide (PEBA) such as those sold

commercially under the PEBAX® trademark by companies such as Elf Atochem, in particular PEBAX® 63D or 70D; and PEBAX® 40D (Shore D scale). In a preferred embodiment, the proximal, intermediate, and distal outer member sections 121, 124, and 127 will have a longitudinal dimension ranging from about 100 to about 125 cm, from about 25 to about 50 cm, and from about 10 to about 35 cm, respectively, and preferably, being about, 125, 25, and 10 cm, respectively. The outer tubular member 43, preferably, will have an outer diameter ranging from about 0.044 to about 0.054 in, and more preferably, being about 0.050 in, although the outer diameter of the outer tubular member 43 may also taper in the distal direction. The outer tubular member 43, preferably, will have an inner diameter ranging from about 0.034 to about 0.044 in, more preferably, being about 0.040 in.

The inner tubular member 46 includes multiple sections, such as, the proximal inner member 145 and the distal inner member 148, the sections decreasing in stiffness in the distal direction. In the embodiment featured in Fig. 5(A), the proximal inner member 145 is necked down at a distal end 151 to form an inner member junction 154 with a proximal end 157 of the distal inner member 148. Preferably, the junction 154 is located along the longitudinal axis of the catheter 13 within either the proximal or the intermediate outer tubular members, 121 and 124. More preferably, the junction 154 does not coincide with the junctures between the intermediate outer member 124 and the proximal and distal outer members 121 and 127..

The multiple stage (sectioned) inner tubular member 46 with a relatively stiff proximal inner member 145 and a relatively flexible distal inner member 148 improves the compressive loading efficiency

of the catheter 10 while minimizing the floppiness of the overall inner member 46 resulting in less deflection of the catheter tip 25 (Fig. 1) when being advanced through the anatomy. Additionally, by placing the junction 154 within a relatively stiff outer tubular member 43, in other words the proximal 121 or the intermediate 124 outer tubular members, the bending stiffness dislocation at the inner member junction 154 is minimized.

In a preferred embodiment, the proximal and distal inner member sections 145 and 148, will be formed of material having flexural modulus in a range from about 50 to about 200 $x10^4$ lb/in^2, and from about 1.3 to about 5 $lb/in^2 x10^4$. Preferred material for forming sections 145 and 148 include, respectively, PEEK, and a co-extrusion comprising PEBA (e.g. PEBAX 40D) and high density polyethylene (HDPE) with a layer of an ethylene and acrylic acid copolymer such as PRIMACOR 1420 therebetween. In a preferred embodiment, the proximal and distal inner member sections 145 and 148 will have a longitudinal dimension ranging from about 125 to about 140 cm and from about 20 to about 35 cm, respectively, preferably, being about 135 and 25 cm, respectively. The inner tubular member 46, preferably, will have an outer diameter ranging from about 0.020 to about 0.035 in, although outer diameter of the inner tubular member 46 may also taper in the distal direction. The inner tubular member 46, preferably, will have an inner diameter ranging from about 0.016 to about 0.020, and more preferably, from about 0.016 to about 0.018 in. Additionally, the distal inner member 148 may be necked down, preferably, to an OD of about 0.020 and an ID of about 0.016 at a location proximal to the proximal end of the inflatable member at about 5 cm from the distal tip of the catheter.

In a preferred embodiment, features of which are illustrated in Fig. 5(B), the stiffness ratio between any two adjacent portions is no less than about 0.3, more preferably, between about 0.3 to about 0.7, and most preferably, at least about 0.7 or greater. For example, the stiffness ratio between point "A" and point "B" is about 1 to about 0.64; between points "B" and "C" is about 1 to about 0.3; and between points "C" and "D" is about 0.76 to about 1; with points "A", "B", "C", and "D" being along the following portions of the catheter, respectively; the proximal outer tubular section 121 and the proximal inner tubular member 145; intermediate outer tubular section 124 and the proximal inner tubular section 145; distal outer tubular section 127 and distal inner tubular section 148; and the stent receiving portion 94 with a stent mounted thereon (including other members that may be present in this portion such as inner member, marker, etc.).

In one embodiment, features of which are illustrated in Fig. 6(A), the catheter shaft 13 at one or more portions of the distal inner member 148 extending through the inflatable member 28 includes at least one tubular sleeve 160 disposed about and attached to the distal inner member 148, preferably, a proximal sleeve 163 and a distal sleeve 166. When a stent 34 is present on the catheter, the one or more tubular sleeve 160 has sufficient stiffness to provide a relatively smooth stiffness transition from a point along the catheter shaft 13 proximal to a proximal edge 169 of the stent 34 to the proximal edge 169 of the stent 34, and from the distal edge 172 of the stent 34 to a point along the catheter shaft 13 distal to the distal edge 172 of the stent 34. Additionally, one or more of the tubular sleeves 163 and 166 may also protect the proximal and distal edges 169 and 172 of the stent 34 by providing extra support in the stiffness transition areas. The proximal and distal tubular sleeves 163 and 166 will be of

sufficient outer diameter to aid in holding the stent 34 in the desired location and minimize risk of loss during insertion into the vasculature.

Preferably, as illustrated in Fig. 6(A), the proximal sleeve 163 extends proximally to the distal edge 175 of the distal outer member 127 and the distal sleeve 166 extends distally to a proximal edge 178 of the distal balloon shaft 118. The tubular sleeves 163 and 166 may be attached to the distal inner member 148 using a heat-based process and they may be tapered on their respective ends, with the amount of taper designed to provide optimum performance.

The tubular sleeve member 160 is formed of material having a flexural modulus ranging from about 1.3 to about 1.7 $x10^4$ lb/in^2. Suitable materials for forming the tubular sleeve 160 include the same material as those used to form the distal inner member 148, but of softer variety. Exemplary material for use as tubular sleeve 160 include, but are not limited to 40D to 70D, such as PEBAX 40D, 63D, or 70D, preferably 40D to 65D. The tubular sleeve 160, preferably, has a wall thickness ranging from about 0.002 to about 0.005 in.

In another embodiment, features of which are illustrated in Fig. 6(B), the proximal and distal tubular sleeves, 163 and 166, may be used in conjunction with proximal and distal markers. When used in cooperation with markers, as illustrated in Fig. 6(B), the tubular sleeves 163 and 166, will preferably extend distal to the proximal edge 169 of the stent 34 (or proximal receiving end 97) and will extend proximal to the distal edge 172 of the stent (or distal receiving end 100) to minimize kinking.

In a preferred embodiment a proximal end 181 of the proximal tubular sleeve 163 is extended into a distal end 184 of the distal outer tubular member 127 forming a proximal overlap region 187 to minimize proximal transition kinking. On the other hand, to minimize

the impact of the proximal overlap 187 on inflation/deflation of the inflatable member 28, the overlap 187 is located within the proximal taper section 109 of the inflatable member 28 by extending a portion 190 of the distal end 184 of the distal outer tubular member 127 into the proximal taper section 109. Preferably, as illustrated in Fig. 7, the distal end 184 of the distal outer tubular member 127, and thus the proximal overlap 187, extends proximally at least to the proximal edge of the proximal tubular sleeve 163, and more preferably, overlaps at least partially with the proximal tubular sleeve 163. The extended portion 190 of the distal outer member 127 can include slices, holes, perforations or grooves.

In another embodiment, an extended distal portion 190 of the distal outer member 127 is extended into the balloon interior chamber 52 such that the distal edge 175 of the distal outer member 127 extends at least to the same longitudinal location as the distal end of the proximal seal 79. Preferably, as illustrated in Fig. 8A, the distal outer member 127 is extended into the balloon intermediate section 85 such that the distal edge 175 of the distal outer member 127 extends at least to the same longitudinal location as the proximal edge 169 of the stent 34 (or proximal receiving end 97). More preferably, the distal edge 175 of the distal outer member 127 terminates distal to the proximal edge 169 of the stent 34 (or proximal receiving end 97), as illustrated in Fig. 8A. Extending the distal outer tubular member 127 to or distal to the proximal edge 169 of the stent 34 (or proximal receiving end 97) is an effective way of distributing bending moment across the proximal end of the balloon. In Fig. 8A, the uninflated balloon is illustrated in phantom lines. Optionally, as illustrated in Fig. 8B, when the proximal edge 169 of the stent 34 ends on a marker such as proximal marker 196, the distal edge 175 of

the distal outer member 127 can extend to the proximal edge of the proximal marker 169.

In one embodiment, as illustrated in Fig. 8C and 8D, at least a portion of the extended distal portion 190 includes perforations 191 or grooves 192 to either or both facilitate passage of inflation fluid to and from the balloon interior chamber 52 as may be necessary and change the stiffness of the catheter. The perforations 191 can have different shapes, such as circular or oblong. In another embodiment, the inner tubular member 46 (Fig. 9) includes at least one radiopaque marker 193 formed of material including at least in part material such as platinum, gold, tungsten, or tantalum, such that during the medical procedure, the location of the stent 34 within the stent delivery system 37 is identifiable through the use of fluoroscopy.

In an embodiment features of which are illustrated in Fig. 9, there is a proximal marker 196 and a distal marker 199 disposed about the distal inner member 148 within the balloon intermediate section 85.

Preferably, as illustrated in Fig. 9, at least a portion of the proximal and distal markers 196 and 199 is positioned within the receiving portion 94 of the inflatable member 28 with at least a portion being outside the receiving portion 94. For example, a proximal portion 202 of the proximal marker 196 extends proximal to the proximal edge 169 of the stent 34 when the stent 34 is mounted on the catheter (or proximal receiving end 97) with a distal portion 205 of the proximal marker 196 extending distally within the receiving portion 94.

Additionally, a distal portion 208 of the distal marker 199 extends distal to the distal edge 172 of the stent 34 (or distal

receiving end 100) with a proximal portion 211 of the distal marker 199 extending proximally within the receiving portion 94.

As illustrated in Figs. 10(a) through 10(d), one or all of the markers 193 may be in contact with at least one jacket 214 such as proximal jacket 217 or distal jacket 220, the jackets, preferably, formed of a flexible material. The jackets 217 or 220 may overlay, partially (Fig. 10(a)) or completely (Fig. 10(b)), the proximal and distal markers, 196 and 199. Alternatively, as illustrated in Fig. 10(c), one jacket 214 may overlay both proximal and distal markers 196 and 199.

Additionally, as illustrated in Fig. 10(D), either or both the proximal and distal jackets 217 and 220 may comprise of an outer layer 229 and an inner layer 232, a portion of the inner layer 232 being adjacent the distal inner member 148 with the inner layer 232 partially overlaying and the outer layer 229 completely overlaying its respective marker, e.g., proximal marker 196.

Alternatively, additional proximal outer jacket 235 of relatively stiffer material (Fig. 10(E)) than the proximal jacket 217 may butt up to the proximal marker 196 without overlapping the proximal marker 196. For example, the outer jacket 235 may butt up to the proximal edge 223 of the proximal marker 196 and an additional distal outer jacket 238 may butt up to the distal edge 226 of the distal marker 199. Preferably, as illustrated in Fig. 10(E), the proximal jacket 217 and the distal jacket 220, overlay the proximal outer jacket 235 and the proximal marker 196, and the distal outer jacket 238 and the distal marker 199, respectively.

When present, the proximal jacket 217 extends at least proximal to a proximal edge 223 of the proximal marker 196, preferably extending beyond the proximal edge 223 of the proximal marker 196,

and most preferably, extending proximally beyond the inflatable member intermediate section 85; and the distal jacket 220 extends at least distal to a distal edge 226 of the distal marker 199, preferably extending beyond the distal edge 226 of the distal marker 199, and most preferably, extending distally beyond the inflatable member intermediate section 85, as illustrated in Fig. 9, above, and Fig. 11.

The jackets 217 or 220, alone or in combination with the relatively stiffer outer jacket 235 or 238, gradually transition the bending stiffness of the distal inner member 148 to the stiffness of the region of the inner tubular member that includes the markers, in particular when a stent 34 is mounted on the catheter.

Now referring to Fig. 12, at least one collar 239, formed of a material comprising, at least in part, a radiopaque material with an increasing outer diameter in the distal direction may be used to provide both the function of the marker 193 and the jacket 214. Preferably, as illustrated in Fig. 12, a proximal 240 and a distal collar 242 is conical in shape with opposite conicities, toward the proximal and distal ends of the catheter, respectively. The proximal and distal collars, 240 and 242, preferably, are of sufficient outer diameter to aid in holding the stent 34 in the desired location and minimize risk of loss during insertion into the vasculature. Exemplary material for forming the collar 239 include, but are not limited to, a radiopaque material such as tantalum or tungsten in a polymeric matrix.

Alternatively, the collar 239 may be integral with the inner tubular member such that the inner tubular member at the desired location has the necessary radiopacity while imparting the desired stiffness profile.

In an embodiment illustrated in Fig. 13(A), a distal junction 70a formed between the distal extremity 61 of the inflatable balloon 28

and the distal extremity 64 of the distal inner member 148 includes perforations 241. The perforations 241 may be formed using a laser or mechanical punch, as is known in the art to process catheter material. The perforations 241, may be formed on the distal shaft 118 of the balloon 28 prior to forming the distal seal 67, (fusion or adhesion bonded), to form the distal junction 70a.

Alternatively, as illustrated in Fig. 13(B) and 13(C), the perforations 241 at the distal junction 70b (Fig. 13(B)) or the grooves 244 at the distal junction 70c (Fig. 13(C)) may be formed after the distal seal 67 has been formed between the distal extremity 61 of the balloon 28 and the distal extremity 64 of the distal inner member 148.

The distal perforations 241 and grooves 244 may or may not extend through to the inner member lumen 55 of the distal inner member 148.

In another embodiment illustrated in Fig. 14, the distal junction 70d may include a taper 247, with or without the perforations 241 (such as those in Fig. 13(B) and grooves 244 (as illustrated in Fig. 14, the distal junction 70d includes grooves 244). The tapered distal junction 70d, decreases in diameter from a proximal end 250 of the distal balloon shaft 118 to a point along the distal junction 70d and may extend distally to a distal end 253 of the distal inner member 148. The taper 247 can be applied after the sealing process using methods such as a heated mold. The perforations 241, grooves 244, and the tapered distal junction 70d improve the flexibility transition of the catheter and may be used individually or in combination with one another.

In another preferred embodiment illustrated in Fig. 15(A), the catheter tip 25, further includes an atraumatic distal tip 256 formed of suitable material such as those having a flexural modulus ranging from

about 1.3 to about $1.7x10^4$ lb/in^2 such as PEBAX 40D. The atraumatic distal tip 256 is, preferably, butt-joined at a proximal end 257 to a distal end 259 of the distal inner member 148. Additionally, an outer sleeve 262 formed of flexible material such as PEBAX 55D or 63D may also be butt-joined to a distal end 265 of the balloon 28 at a point proximal to the distal end 259 of the inner tubular member 148 and extends distally to a point proximal to a distal end 268 of the atraumatic distal tip 256. Fig. 15(B) illustrates the catheter tip of Fig. 15(A) after the members have been heat sealed, having a preferred tapered profile.

The presence of the atraumatic distal tip 256 and the optional outer sleeve 262, provide for a smoother decrease in the bending stiffness of the catheter tip 25 in the distal direction.

In another embodiment, features of which are illustrated in Fig. 15(C), the distal end 259 of the distal inner member 148 terminates proximal to the proximal end 178 of the distal balloon shaft 118. Preferably, a proximal section 269 of the atraumatic tip 256 extends proximally within the balloon interior chamber 52 overlaying a distal portion 270 of the distal inner member 148. More preferably, the atraumatic tip proximal end 257 extends up to the distal end of the distal marker 199 when present; most preferably, overlaying the distal marker 199.

In one embodiment illustrated in Fig. 16, an inner member 46' comprises, at least in its distal section 148', a tubular member 271 with an imbedded coil 274 for providing a gradual change in stiffness profile of the catheter near and at the stent region. The coil 274 may have variable pitch 277 along its length. As can be seen in Fig. 16, the coil 274 may have a relatively open pitch at a first point 278 near the balloon proximal end, the pitch 277 becoming tighter in the distal

direction toward the proximal edge 169 of the stent 34 (when a stent is mounted on the catheter), with a tight pitch 279 near or at the stent proximal edge 169. The pitch 277, becomes more open as the coil 274 moves distally away from the proximal edge 169 of the stent, and becoming tighter at a second tight pitch point 279' near or at the distal edge 172 of the stent 34. The pitch again opens as the coil 274 moves distally away from the distal edge 172 of the stent 34. The tubular member 271 or the coil 274 may be formed of radiopaque material in the appropriate areas, such as tight pitch points 279 and 279' near the ends of the stent, thereby acting as a marker.

In another embodiment illustrated in Fig. 17, at least a portion of the catheter 10, includes a sheath 280 disposed over, at least part of, the stent 34, the sheath 280 being retractable prior the deployment of the stent 34 in the desired area. The sheath 280 may be selectively stiffened by various means to minimize kink points near or at the ends of the stent 34. The variable stiffness of the sheath 280 may be achieved by, varying a wall thickness 283 of the sheath, varying the material from which the sheath 280 is formed, including an imbedded coil 286 with different pitch 289 along its length as shown in Fig. 18, or varying the outer diameter of the sheath 280.

The stent deploying balloon 28 of the invention can be produced by conventional techniques for producing catheter inflatable members. In a presently preferred embodiment, the balloon is formed within a mold having the general shape of the expanded balloon illustrated in Fig. 4. An extruded polymeric tube is radially expanded and axially expanded within the mold, at elevated temperatures, and may be heat treated one or more times as is conventionally known as, for example, to reduce shrinkage of the balloon. The balloon is secured to the catheter shaft, and is typically folded thereon into a low profile

configuration for insertion and advancement within the body lumen of the patient.

The presently preferred balloon material is a polyamide such as polyether block amide, such as those available under the trade designation of PEBAX, such as PEBAX 70D or 63D. However, other suitable materials may be used including polyamide copolymers such as Nylon 12 , polyethylenes, and polyurethanes such as PELLETHANE (a polyurethane copolymer). The balloon material may be cross-linked or not, depending upon the nature of the material and characteristics required for a particular application. The presently preferred PEBAX balloon material is not cross-linked. By cross-linking the balloon compliant material, the final inflated balloon size can be controlled. Conventional cross-linking techniques can be used including thermal treatment and E-beam exposure. After cross-linking, initial pressurization, expansion, and preshrinking, the balloon will thereafter expand in a controlled manner to a reproducible diameter in response to a given inflation pressure, and thereby avoid over-expanding the stent to an undesirably large diameter.

The length of the compliant balloon 28 may be from about 0.5 cm to about 6 cm, preferably from about 1.0 cm to about 4.0 cm. With the balloon folded in a low profile configuration for introduction into and advancement within a patient's vasculature, the outer diameter of the balloon catheter at the stent-receiving portion of the balloon 94 with a stent 34 thereon is about 0.040 to about 0.050 in. In an expanded state, the wall thickness is about 0.0005 to about 0.0010 in. The balloon 28 may be provided in a variety of sizes. The inflated outer diameter of the balloon stent-receiving portion 94 within the deployment pressure is about 2.0 to about 5.0 mm. The inflated outer diameter of the proximal and distal intermediate portions 103

and 106 within the deployment pressure is about 100% of that for the stent-receiving portion 94 within the deployment pressure. In a presently preferred embodiment, the length of the intermediate section 85 ranges from about 9 to about 41 mm; the length of the stent-receiving portion 94 ranges from about 8 to about 40 mm; and the length of the proximal and distal tapered areas ranges from about 2 to about 6 mm. The length of the proximal and distal shafts 115 and 118 in a preferred embodiment ranges from about zero to about 1 mm.

In the embodiment illustrated in Figs. 4, the balloon 28 is symmetrical and the stent-receiving portion 94 is at a central location on the balloon 28. However, alternative balloon designs may be used for particular applications and anatomies.

The stent 34 may be any of a variety of stent materials and forms designed to be implanted by an expanding member, such as, for example, the MULTI-LINK™ stent, commercially available from Guidant Corporation, and the stents described in U.S. Patent 5,514,154 (Lau *et al.*) and 5,443,500 (Sigwart), incorporated herein by reference in their entireties. For example, the stent material may be stainless steel, a NiTi alloy, a Co-Cr-Mo containing alloy such as MP-35N, a plastic material, or various other materials. The stent has a smaller diameter for insertion and advancement into the patient's lumen which may be formed by contracting the stent or by folding at least a portion of the stent into a wrapped configuration. It should be noted that the stent 34 may be self or balloon deployable.

By way of example, and not as a limitation, the following example is offered:

The optimization of bending stiffness and kink resistance can be observed in a force-displacement graph of a test performed with a

neurovascular stent delivery system, NSDS, embodying some of the features of the present invention, and two commercially available coronary stent delivery systems, CSDS 1 AND CSDS 2. The catheters were pushed through a tight radius (e.g., a radius of curvature of about 5mm with an angle of curve of about 90°) vascular model at a constant rate of speed. A force transducer measured the resistance force of the catheter passing through the model. The applied force through the entire catheter was then plotted against the distance the catheter was advanced through the model, as illustrated in Fig. 19.

Crossing force is a function of, among other things, surface friction and bending stiffness. The various peaks on the graph of Fig. 19, occur when stiff, rigid sections of the catheter device are attempting to pass through the radius of the model. The height of the peak is determined in part by the stiffness and length of the rigid section, and the presence of a kink just distal to the rigid section. For this experiment, the lengths of the different catheter portions among the different catheters did not vary, with the exception of the catheter of the present invention including the atraumatic distal tip and the outer layer member. As can be seen in Fig. 19, three main peaks can generally be observed along each plot. Moving from left to right on the plots, the first (E, E', E''), second (F, F', F''), and the third (G, G', G'') peaks correspond to a point along the catheter, respectively, at or about the distal balloon seal, at the stent area, and at or about the proximal balloon seal, with the designations E, E', and E''; F, F', B''; G, C', G'' corresponding, respectively, to:

NSDS of the present invention;

CSDS 1 available from Guidant Corporation under the trade designation ACS Multi-Link OTW Duet™ Coronary Stent System;

CSDS 2 available from Guidant Corporation under the trade designation ACS Multi-Link OTW Tristar™ Coronary Stent System.

The effect of the marker bands on the two commercial catheters may not be as observable due to the relatively stiffer catheters. Although very stiff, the length of the marker band is relatively short and compared to the relatively stiffer coronary catheters the kink points are not as discernable. On the softer neuro stent delivery system of the present invention, the kink points along the catheter at a location corresponding to the marker bands can be improved utilizing other embodiments described above, such as crimping the stent on the marker bands and adding the jackets to the inner member.

When reviewing Fig. 19, it should be noted, that although the crossing force profile is dependent on the bending stiffness, it is also a function of other parameters such as, surface friction and length of rigid sections.

As can further be observed from Fig. 19, at all stages of the catheter, the magnitude of force required to push the coronary devices, as well as the amplitude, is much greater than the same for the neuro stent delivery system of the present invention. Furthermore, the slope (i.e., transition between points of differing stiffness along the catheter) of the curves leading to the peaks and valleys are less severe for the catheter of the present invention.

While particular forms of the invention have been illustrated and described, it will be apparent that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

CLAIMS

WHAT IS CLAIMED IS:

1. A stent delivery system, comprising:

a catheter having an elongated shaft with proximal and distal ends and an inner lumen extending therein;

an enlargeable member mounted on a distal shaft section proximal to the distal end which is configured for supporting a deployable prosthetic device on a receiving portion thereon, which has an interior in fluid communication with the inner lumen;

a tubular member extending through the interior of the enlargeable member;

proximal and distal radiopaque markers disposed on a portion of the tubular member extending within the interior of the enlargeable member, with a portion of each marker being within the receiving portion of the enlargeable member; and optionally at least one jacket disposed on a portion of the tubular member extending within the interior of the enlargeable member and overlaying, at least in part, at least one of the proximal and distal markers, the jacket extending, at least in part, outside the receiving portion of the enlargeable member.

2. The system of Claim 1 wherein the at least one jacket is one continuous member overlying both the proximal and the distal markers.

3. The system of Claim 1 wherein the at least one jacket includes a proximal and a distal jacket overlaying, at least in part, the proximal and the distal markers, respectively.

4. The system of Claim 1 wherein the enlargeable member further includes a proximal and a distal section and an intermediate section therebetween, the intermediate section including the receiving portion, and wherein the at least one jacket extends proximally beyond the enlargeable member intermediate section, preferably the enlargeable member proximal section includes a proximal shaft at its most proximal portion terminating at a proximal end of the enlargeable member, the proximal enlargeable member shaft having a proximal end and a distal end, and the proximal jacket extends proximally to the distal end of the proximal enlargeable member shaft, or the enlargeable member further includes a proximal and a distal section and an intermediate section therebetween, the intermediate section including the receiving portion, and wherein the at least one jacket extends distally beyond the enlargeable member intermediate section, preferably the enlargeable member distal section includes a distal shaft at its most distal portion terminating at a distal end of the enlargeable member, the distal enlargeable member shaft having a proximal end and a distal end, and the distal jacket extends distally to the proximal end of the distal enlargeable member shaft.

5. The system of Claim 4 wherein the enlargeable member receiving portion includes proximal and distal ends wherein the catheter has a gradual change in bending stiffness, preferably an increase, from a first point along the catheter having the same

transverse location as a point along the enlargeable member proximal section to a second point along the catheter having the same transverse location as the proximal receiving end of the enlargeable member receiving portion, or optionally the catheter has a gradual change in the bending stiffness, preferably an increase, from a third point along the catheter having the same transverse location as the distal receiving end of the enlargeable member receiving portion to a fourth point along the catheter having the same transverse location as a point along the enlargeable member distal section.

6. The system of Claim 1 wherein the at least one jacket includes an outer and an inner layer, a portion of the inner layer being adjacent the tubular member extending through the interior of the enlargeable member, preferably the inner layer partially and the outer layer completely overlay at least one of the proximal and distal markers, respectively.

7. The system of Claim 1 further including at least one outer jacket formed of a material relatively stiffer than the jacket material and butting up to at least one of the proximal and distal markers, the at least one outer jacket being overlaid, at least partially, with the jacket.

8. A stent delivery system, comprising:

a catheter having an elongated shaft with proximal and distal ends and an inner lumen extending therein, the catheter having more than one portion with different stiffness values, each portion comprising of components that gradually transition the stiffness of that portion to an adjacent portion, preferably at least one portion is stiffer than a portion immediately proximal to

the at least one portion, wherein the immediately proximal portion includes components that gradually transition the stiffness of the immediately proximal portion to the at least one portion;

an enlargeable member mounted on a distal shaft section proximal to the distal end which is configured for supporting a deployable prosthetic device on a receiving portion thereon, which has an interior in fluid communication with the inner lumen, preferably the enlargeable member has proximal and distal ends, and wherein the more than one portion having different stiffness values is disposed longitudinally along a first section of the catheter between first and second points, the first and second points having the same transverse location as the enlargeable member proximal end and distal ends, respectively, each portion comprising of components that gradually match the stiffness of that portion to an adjacent portion;

a tubular member extending through the interior of the enlargeable member, preferably at least a portion of the tubular member extending within the interior of the enlargeable member includes a tubular member with an imbedded coil for providing a gradual transition in stiffness of that portion to the enlargeable member receiving portion upon receiving the deployable member thereon, and optionally

proximal and distal radiopaque markers disposed on a portion of the tubular member extending within the interior of the enlargeable member, preferably a portion of each marker being within and a portion being outside the receiving portion of the enlargeable member; and further optionally

a deployable member disposed on the enlargeable member receiving portion, and optionally a retractable sheath disposed over at least a portion of the catheter shaft including the deployable member, preferably the sheath has a variable stiffness to minimize kinking of the catheter near or at proximal and distal ends of the deployable member.

9. The system of Claim 8 wherein the catheter shaft comprises an outer tubular member and an inner tubular member, the outer tubular member including more than one section, the sections having a decrease in stiffness in the distal direction, preferably the outer tubular member includes a proximal, an intermediate, and a distal outer member, the members having a lower stiffness value than the section immediately proximal thereto, preferably the inner tubular member includes proximal and distal inner tubular members, the distal inner tubular member having a lower stiffness value than the proximal inner tubular member.

10. A stent delivery system, comprising:

a catheter having an elongated shaft with proximal and distal ends and an inner lumen extending therein;

an enlargeable member mounted on a distal shaft section proximal to the distal end which is configured for supporting a deployable prosthetic device thereon, which has an interior in fluid communication with the inner lumen, preferably the enlargeable member includes a deployable member receiving portion having proximal and distal receiving ends with the at least one radiopaque segment located longitudinally within and outside the deployable receiving portion;

a tubular member extending, at least in part, through the interior of the enlargeable member; and

at least one radiopaque segment having proximal and distal ends and disposed at least in part within the enlargeable member, the catheter shaft having a sufficiently gradual change in stiffness, preferably an increase, from a point proximal to the proximal end of the radiopaque segment to at least the proximal end of the radiopaque segment to minimize kinking of the catheter upon application of force during a medical procedure, preferably the radiopaque segment has a conical shape with a conicity away from the receiving portion or the radiopaque segment is integral with the tubular member extending through the enlargeable member.

11. A stent delivery system, comprising:

a catheter having an elongated shaft with proximal and distal ends and an inner lumen extending therein;

an enlargeable member mounted on a distal shaft section proximal to the distal end which is configured for supporting a deployable prosthetic device thereon, which has an interior in fluid communication with the inner lumen; and

an outer tubular member and an inner tubular member with a distal inner member having a portion extending through the enlargeable member, the extending portion of the distal inner member including at least one tubular sleeve disposed about and attached to the distal inner member, the at least one tubular sleeve having sufficient stiffness to provide a relatively smooth stiffness transition from a point along the catheter shaft

proximal to a proximal edge of the at least one tubular sleeve to a point along the catheter shaft distal to a distal edge of the at least one tubular sleeve.

12. The system of Claim 11 wherein the at least one tubular sleeve is a proximal sleeve providing a smooth stiffness transition from a point along the catheter shaft proximal to a proximal edge of the deployable member to at least the proximal edge of the deployable member upon receiving the deployable member on the enlargeable member, preferably the proximal sleeve extends proximally to a distal edge of the outer tubular member, or the at least one tubular sleeve is a distal sleeve for providing a smooth stiffness transition from at least a distal edge of the deployable member to a point along the catheter shaft distal to the distal edge of the deployable member upon receiving the deployable member on the enlargeable member, preferably the at least one tubular sleeve includes proximal and distal sleeves.

13. The system of Claim 11 wherein the at least one tubular sleeve is of sufficient outer diameter to aid in holding the deployable member in the desired location and minimizing risk of loss during insertion into the vasculature.

14. The system of Claim 12 wherein the enlargeable member includes proximal and distal sections and an intermediate section therebetween, the intermediate section including the deployable member receiving portion, wherein the proximal section includes a proximal shaft at its most proximal end and the distal section includes a distal shaft at its most distal end, the proximal and distal shafts forming fluid-tight seals with the catheter shaft, preferably the proximal tubular sleeve is extended into a distal

end of the outer tubular member forming a proximal overlap region to minimize proximal transition kinking, preferably a portion of the distal end of the outer tubular member is extended into the proximal section of the enlargeable member and the proximal overlap is located within the extended portion, preferably the distal sleeve extends distally to a proximal edge of the enlargeable member distal shaft.

15. The system of Claim 12 further including a proximal radiopaque marker disposed on the distal inner tubular member, a portion of the proximal marker extending within the enlargeable member receiving portion and a portion extending outside the receiving portion, wherein the proximal tubular sleeve extends distal to the proximal receiving end of the enlargeable member, or a distal radiopaque marker disposed on the distal inner tubular member, a portion of the distal marker extending within the enlargeable member receiving portion and a portion extending outside the receiving portion, wherein the distal tubular sleeve extends proximal to the distal receiving end of the enlargeable member.

16. A stent delivery system, comprising:

a catheter having an elongated shaft with proximal and distal ends and an inner lumen extending therein;

an enlargeable member mounted on a distal shaft section proximal to the distal end which is configured for supporting a deployable prosthetic device on a receiving portion thereon, which has an interior in fluid communication with the inner lumen; and

an outer tubular member having a distal edge and an inner tubular member, the distal edge of the outer tubular member extending distally to a point being at the same transverse location or proximal to a proximal end of the receiving portion, preferably the distal edge of the outer tubular member extends distal to the proximal end of the receiving portion.

17. A stent delivery system, comprising:

a catheter having an elongated shaft with proximal and distal ends and an inner lumen extending therein, the catheter having more than one portion with different stiffness values, each portion comprising of components that gradually transition the bending stiffness of that portion to an adjacent portion;

an enlargeable member having proximal and distal ends and mounted on a distal shaft section proximal to the shaft distal end, the enlargeable member having an interior in fluid communication with the inner lumen and configured for supporting a deployable prosthetic device on a receiving portion thereon, the enlargeable member forming proximal and distal fluid-tight seals with the catheter shaft at the enlargeable member proximal and distal ends, respectively, the distal seal having perforations or grooves thereon to provide a gradual stiffness reduction in the distal direction; and

tubular member extending through the interior of the enlargeable member, preferably the tubular member extends distally at least to a point along the enlargeable member distal seal, preferably tapered in the distal direction, and perforations and grooves extend through the inner member lumen.

18. A stent delivery system, comprising:

a catheter having an elongated shaft with proximal and distal ends and an inner lumen extending therein, and a catheter tip at the shaft distal end and including an atraumatic distal tip having a distal end, preferably the catheter tip is tapered.

an enlargeable member having proximal and distal ends and mounted on a distal shaft section proximal to the shaft distal end which is configured for supporting a deployable prosthetic device on a receiving portion thereon, which has an interior in fluid communication with the inner lumen;

a tubular member extending through the interior of the enlargeable member and having a distal end, the tubular member distal end being butt-joined to a proximal end of the atraumatic distal tip; and

an outer layer member butt-joined to the enlargeable member distal end at a point proximal to the tubular member distal end and extending distally to a point proximal to the distal end of the atraumatic distal tip.

19. The system to Claim 18 wherein the tubular member distal end terminates within the interior of the enlargeable member, preferably the atraumatic distal tip has a proximal section extending within the interior of the enlargeable member, more preferably at least a portion of the atraumatic distal tip proximal section overlays at least a portion of the tubular member distal end, and optionally further including a marker disposed on a portion of the tubular member extending within the interior of the enlargeable member, and the atraumatic distal tip proximal

end extends to a distal end of the marker, preferably the atraumatic distal tip proximal section overlays the marker.

20. A balloon catheter, comprising:

a catheter having an elongated shaft with proximal and distal ends and an inner lumen extending therein;

an enlargeable member mounted on a distal shaft section proximal to the distal end, which has an interior in fluid communication with the inner lumen;

a tubular member extending through the interior of the enlargeable member;

proximal and distal radiopaque markers disposed on a portion of the tubular member extending within the interior of the enlargeable member; and

at least one jacket disposed on a portion of the tubular member extending within the interior of the enlargeable member and overlaying, at least in part, at least one of the proximal and distal markers, preferably the at least one jacket is one continuous member overlying both the proximal and the distal markers, preferably the at least one jacket includes a proximal and a distal jacket overlaying, at least in part, the proximal and the distal markers, respectively.

21. The catheter of Claim 20 wherein the enlargeable member further includes a proximal and a distal section and an intermediate section therebetween, and wherein the at least one jacket extends proximally beyond the enlargeable member intermediate section, preferably the enlargeable member proximal section includes a proximal shaft at its most proximal

portion terminating at a proximal end of the enlargeable member, the proximal enlargeable member shaft having a proximal end and a distal end, and the proximal jacket extends proximally to the distal end of the proximal enlargeable member shaft, or the enlargeable member further includes a proximal and a distal section and an intermediate section therebetween, and wherein the at least one jacket extends distally beyond the enlargeable member intermediate section, preferably the enlargeable member distal section includes a distal shaft at its most distal portion terminating at a distal end of the enlargeable member, the distal enlargeable member shaft having a proximal end and a distal end, and the distal jacket extends distally to the proximal end of the distal enlargeable member shaft.

22. The catheter of Claim 20 wherein the at least one jacket includes an outer and an inner layer, a portion of the inner layer being adjacent the tubular member extending through the interior of the enlargeable member, preferably the inner layer partially overlays, and the outer layer completely overlays, at least one of the proximal and distal markers.

23. A balloon catheter, comprising:

a catheter having an elongated shaft with proximal and distal ends and an inner lumen extending therein, the catheter having more than one portion with different stiffness values, each portion comprising of components that gradually transition the stiffness of that portion to an adjacent portion;

an enlargeable member mounted on a distal shaft section proximal to the distal end which has an interior in fluid communication with the inner lumen, preferably the enlargeable

member has proximal and distal ends, and wherein the more than one portion having different stiffness values is disposed longitudinally along a first section of the catheter between first and second points, the first and second points having the same transverse location as the enlargeable member proximal end and distal ends, respectively, each portion comprising of components that gradually match the stiffness of that portion to an adjacent portion;

a tubular member extending through the interior of the enlargeable member, preferably at least one portion is stiffer in bending than a portion immediately proximal to the at least one portion, wherein the immediately proximal portion includes components that gradually transition the stiffness of the immediately proximal portion to the at least one portion; and optionally

proximal and distal radiopaque markers disposed on a portion of the tubular member extending within the interior of the enlargeable member.

24. The catheter of Claim 23 wherein the catheter shaft comprises an outer tubular member and an inner tubular member, the outer tubular member including more than one section, the sections having a decrease in stiffness in the distal direction, preferably the outer tubular member includes a proximal, an intermediate, and a distal outer member, the members having a lower stiffness value than the section immediately proximal thereto or the inner tubular member includes proximal and distal inner tubular members, the distal inner tubular member having a lower stiffness value than the proximal inner tubular member.

25. The catheter of Claim 23 wherein at least a portion of the tubular member extending within the interior of the enlargeable member includes a tubular member with an imbedded coil for providing a gradual transition in stiffness of that portion to an adjacent portion.

26. The catheter of Claim 23 further including a sheath disposed over at least a portion of the catheter shaft including the enlargeable member, preferably the sheath has a variable stiffness to minimize kinking of the catheter near or at the enlargeable member.

27. A balloon catheter, comprising:

a catheter having an elongated shaft with proximal and distal ends and an inner lumen extending therein;

an enlargeable member mounted on a distal shaft section proximal to the distal end which is configured for supporting a deployable prosthetic device thereon, which has an interior in fluid communication with the inner lumen;

a tubular member extending, at least in part, through the interior of the enlargeable member; and

at least one radiopaque segment having proximal and distal ends and disposed at least in part within the enlargeable member, the catheter shaft having a sufficiently gradual change in stiffness, preferably an increase, from a point proximal to the proximal end of the radiopaque segment to at least the proximal end of the radiopaque segment to minimize kinking of the catheter upon application of force during a medical procedure,

preferably the radiopaque segment is integral with the tubular member extending through the enlargeable member.

28. A balloon catheter, comprising:

a catheter having an elongated shaft with proximal and distal ends and an inner lumen extending therein;

an enlargeable member mounted on a distal shaft section proximal to the distal end which has an interior in fluid communication with the inner lumen;

an outer tubular member and an inner tubular member with a distal inner member having a portion extending through the enlargeable member, the extending portion of the distal inner member including at least one tubular sleeve disposed about and attached to the distal inner member, the at least one tubular sleeve having sufficient bending stiffness to provide a relatively smooth bending stiffness transition from a point along the catheter shaft proximal to a proximal edge of the at least one tubular sleeve to a point along the catheter shaft distal to a distal edge of the at least one tubular sleeve, preferably the at least one tubular sleeve includes proximal and distal sleeves, preferably the proximal sleeve extends proximally to a distal edge of the outer tubular member; and optionally

at least one radiopaque marker disposed on the distal inner tubular member.

29. The catheter of Claim 28 wherein the enlargeable member includes proximal and distal sections and an intermediate section therebetween, wherein the proximal section includes a proximal shaft at its most proximal end and the distal section includes a

distal shaft at its most distal end, the proximal and distal shafts forming fluid-tight seals with the catheter shaft, preferably the proximal tubular sleeve is extended into a distal end of the outer tubular member forming a proximal overlap region to minimize proximal transition kinking, preferably a portion of the distal end of the outer tubular member is extended into the proximal section of the enlargeable member and the proximal overlap is located within the extended portion or the distal sleeve extends distally to a proximal edge of the enlargeable member distal shaft.

30. A balloon catheter, comprising:

a catheter having an elongated shaft with proximal and distal ends and an inner lumen extending therein;

an enlargeable member mounted on a distal shaft section proximal to the distal end, the enlargeable member having proximal and distal sections and an intermediate section therebetween, which has an interior in fluid communication with the inner lumen; and

an outer tubular member having a distal edge and an inner tubular member, the distal edge of the outer tubular member extending distally within the point being at the same transverse location or proximal to a proximal end of the intermediate section.

31. A balloon catheter, comprising:

a catheter having an elongated shaft with proximal and distal ends and an inner lumen extending therein, the catheter having more than one portion with different stiffness values,

each portion comprising of components that gradually transition the stiffness of that portion to an adjacent portion;

an enlargeable member having proximal and distal ends and mounted on a distal shaft section proximal to the shaft distal end, the enlargeable member having an interior in fluid communication with the inner lumen, the enlargeable member forming proximal and distal fluid-tight seals with the catheter shaft at the enlargeable member proximal and distal ends, respectively, the distal seal having perforations or grooves thereon to provide a gradual stiffness reduction in the distal direction; and

a tubular member extending through the interior of the enlargeable member, preferably the tubular member extends distally at least to a point along the enlargeable member distal seal and perforations and grooves extend through the inner member lumen, preferably the distal seal is tapered in the distal direction.

32. A balloon catheter, comprising:

a catheter having an elongated shaft with proximal and distal ends and an inner lumen extending therein, and a catheter tip preferably tapered, at the shaft distal end and including an atraumatic distal tip having a distal end;

an enlargeable member having proximal and distal ends and mounted on a distal shaft section proximal to the shaft distal end which has an interior in fluid communication with the inner lumen; a tubular member extending through the interior of the enlargeable member and having a distal end, the tubular member distal end

being butt-joined to a proximal end of the atraumatic distal tip, preferably the tubular member distal end terminates within the interior of the enlargeable member, preferably the atraumatic distal tip has a proximal section extending within the interior of the enlargeable member, more preferably at least a portion of the atraumatic distal tip proximal section overlays at least a portion of the tubular member distal end; an outer layer member butt-joined to the enlargeable member distal end at a point proximal to the tubular member distal end and extending distally to a point proximal to the distal end of the atraumatic distal tip; and optionally a marker disposed on a portion of the tubular member extending within the interior of the enlargeable member, and the atraumatic distal tip proximal end extends to a distal end of the marker, preferably the atraumatic distal tip proximal section overlays the marker.

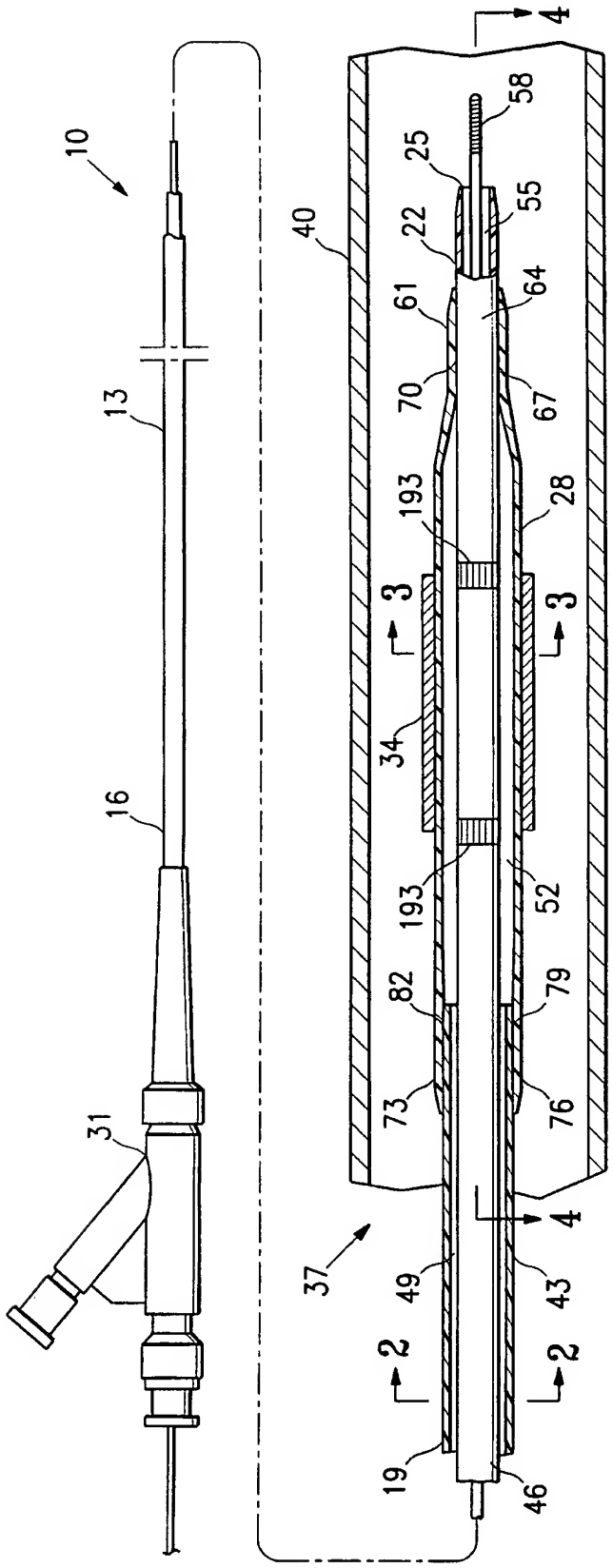


FIG. 1

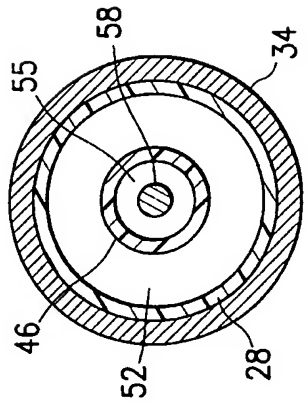


FIG. 3

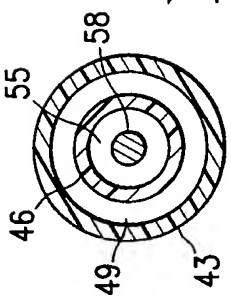


FIG. 2

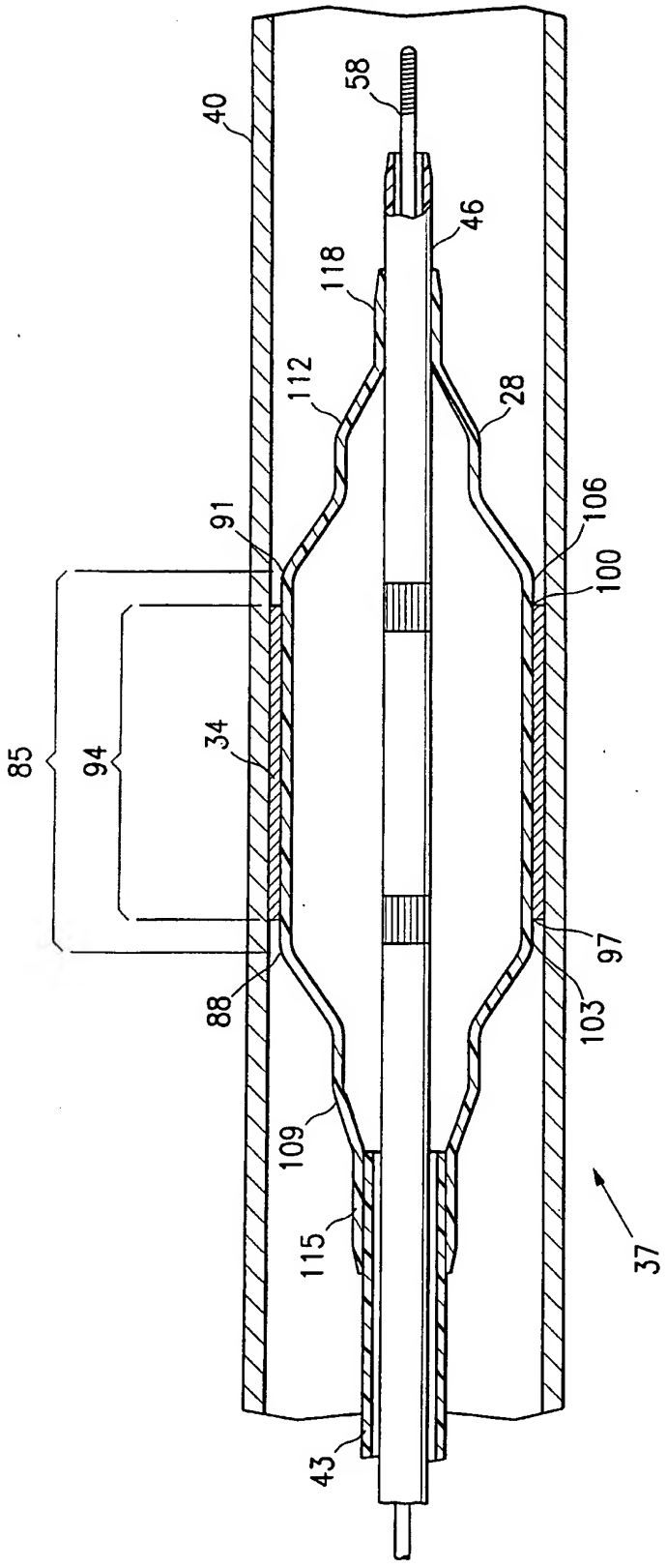
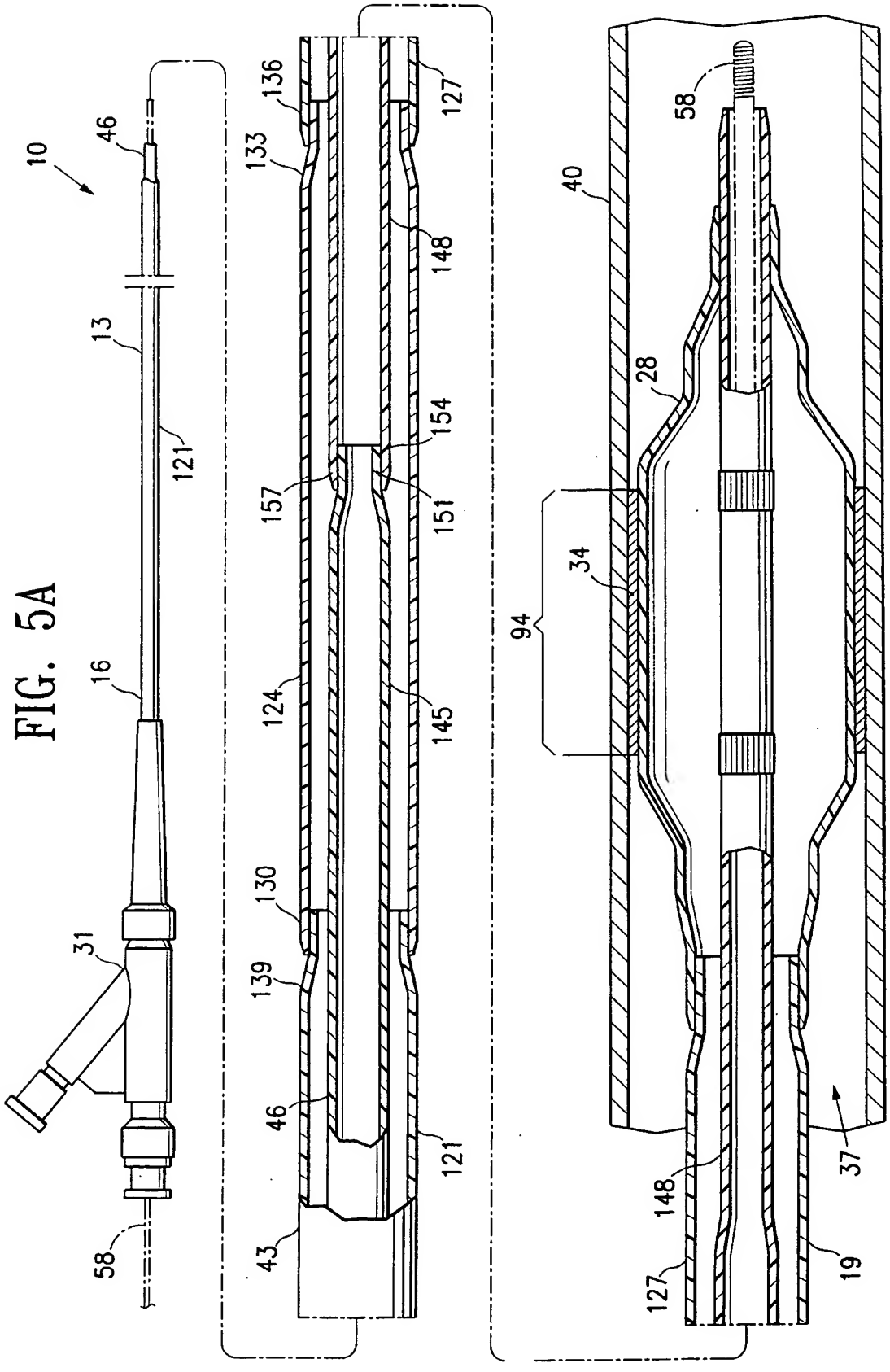


FIG. 4

FIG. 5A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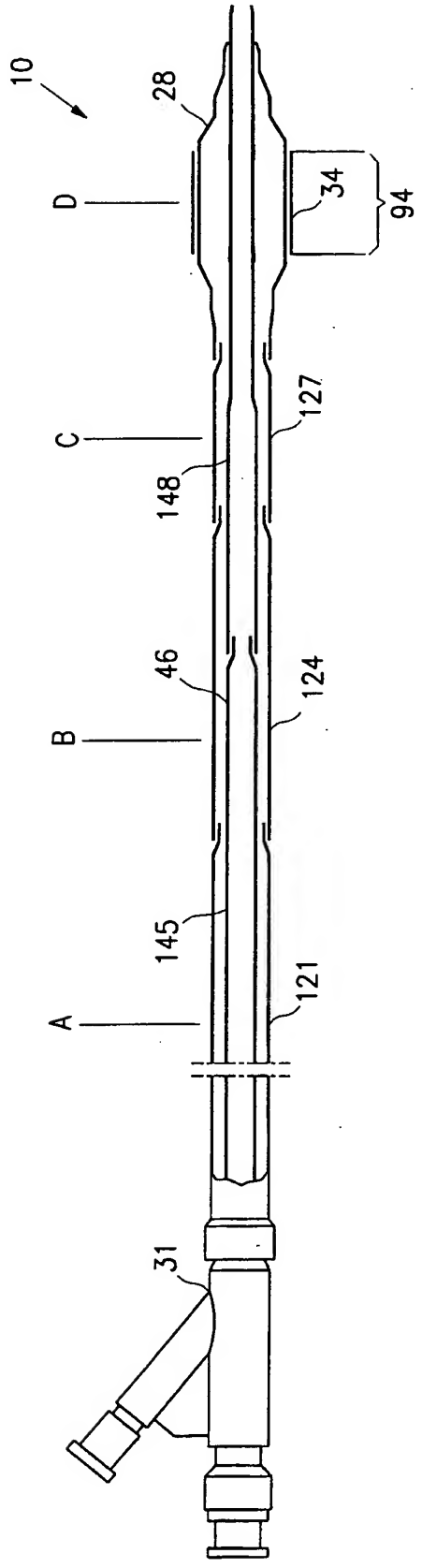

FIG. 5B

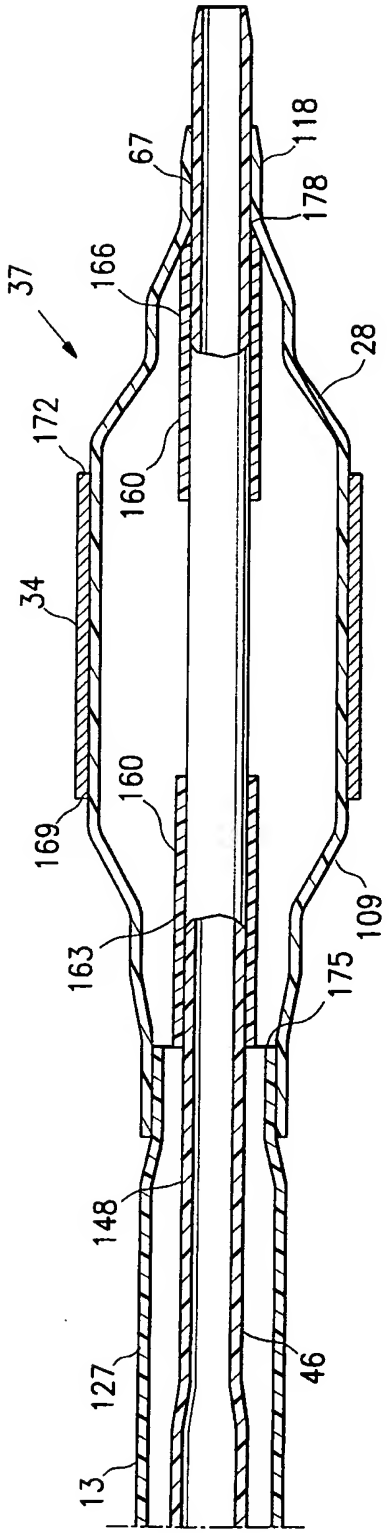
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FIG. 6A

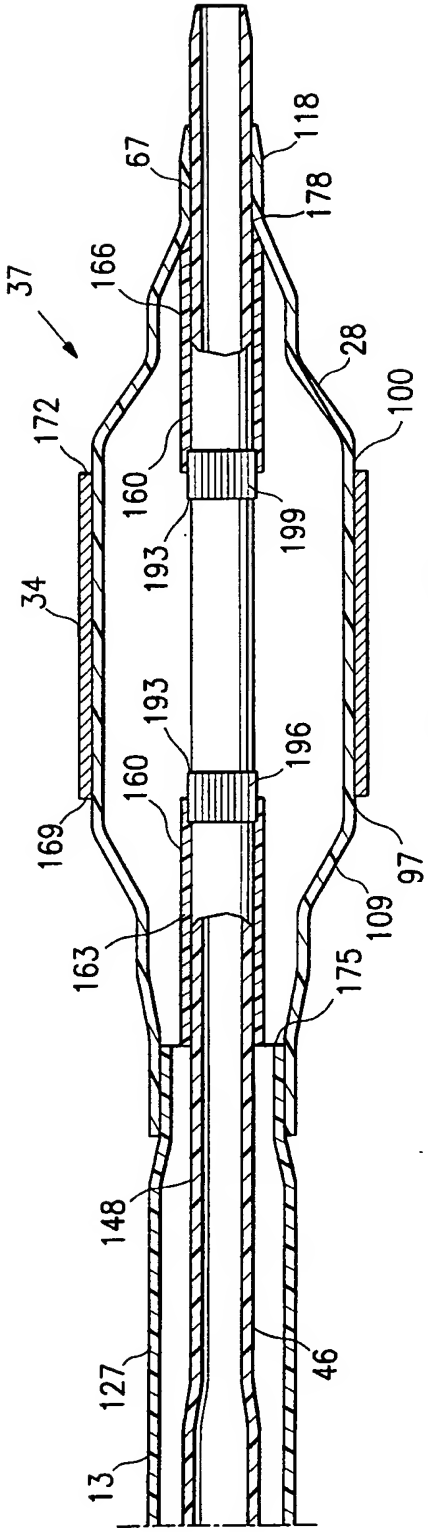
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FIG. 6B

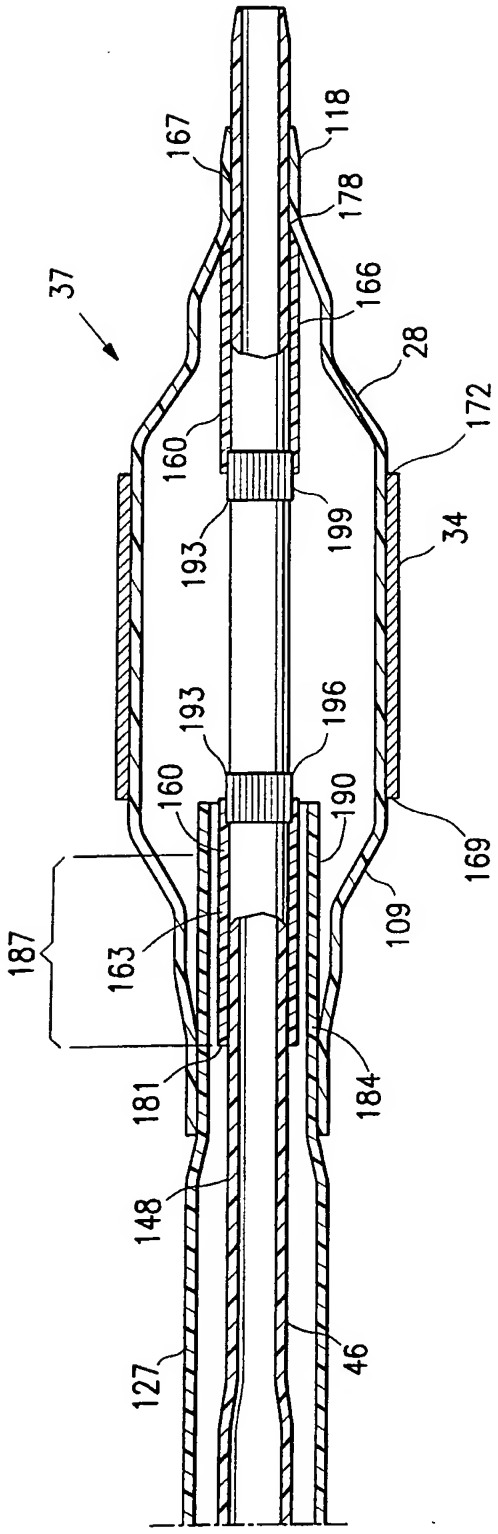
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FIG. 7

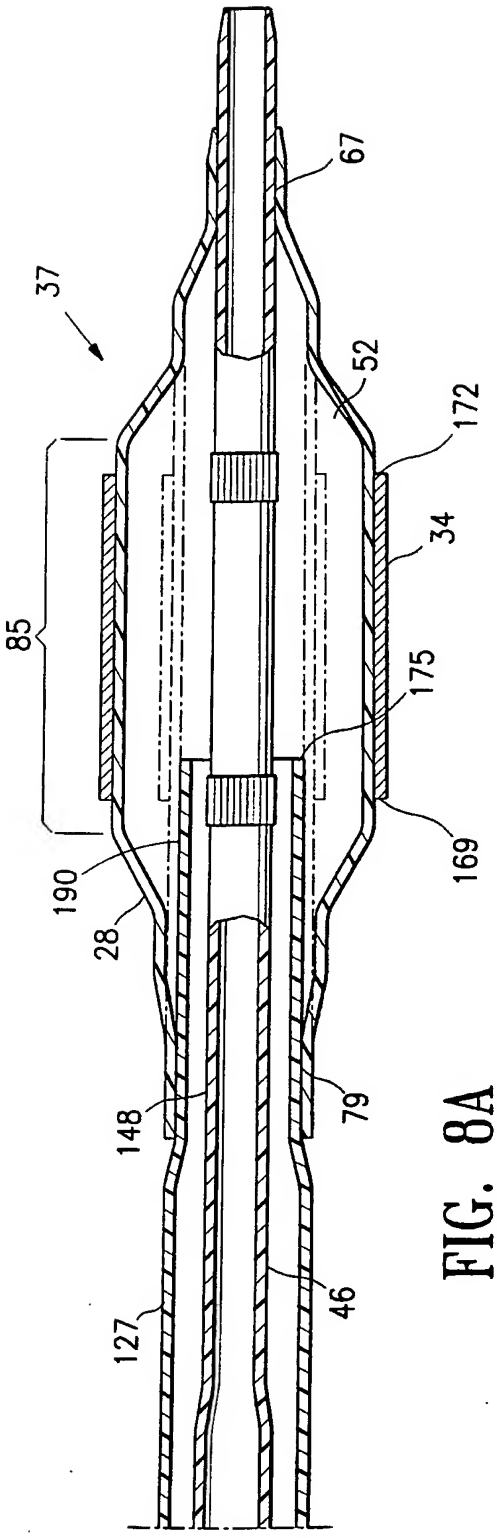
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FIG. 8A

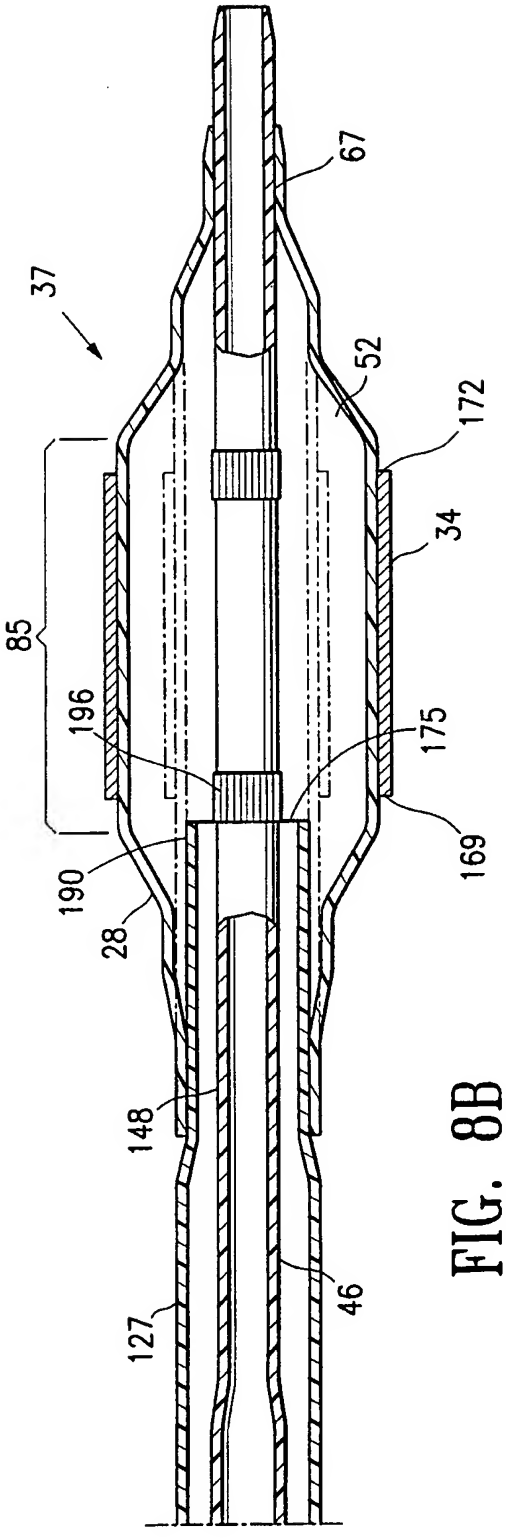
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FIG. 8B

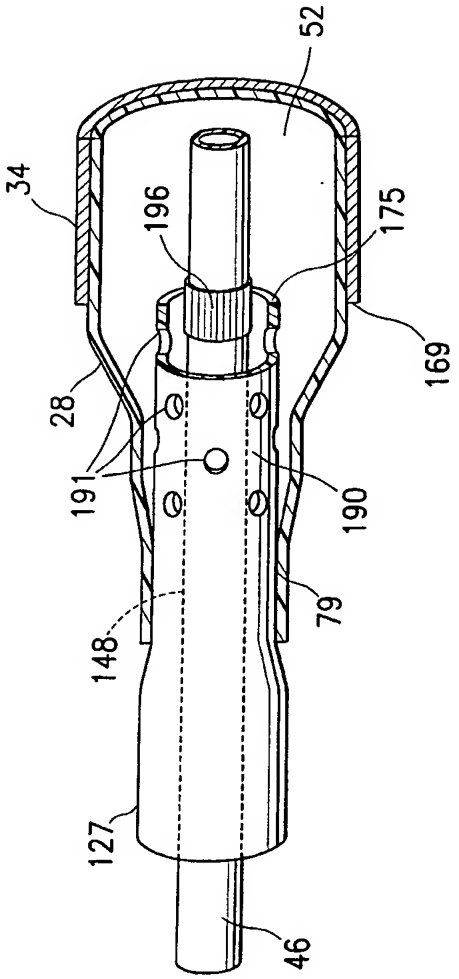
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FIG. 8C

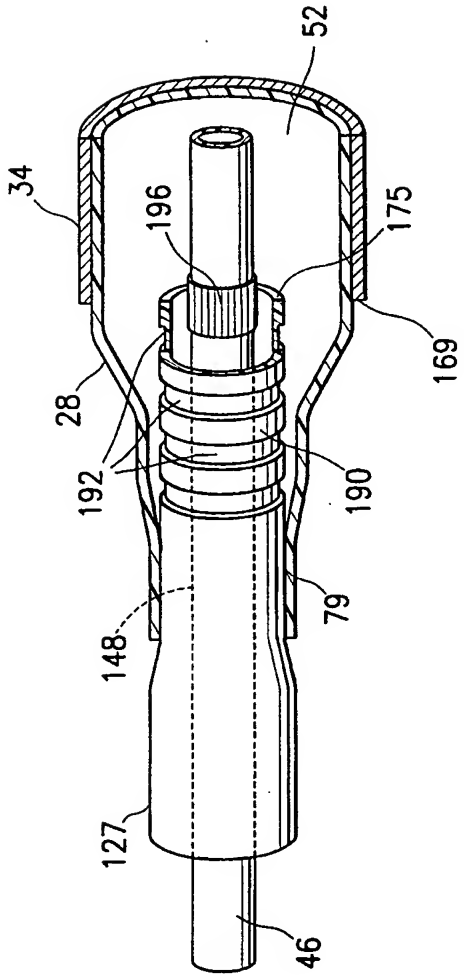
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FIG. 8D

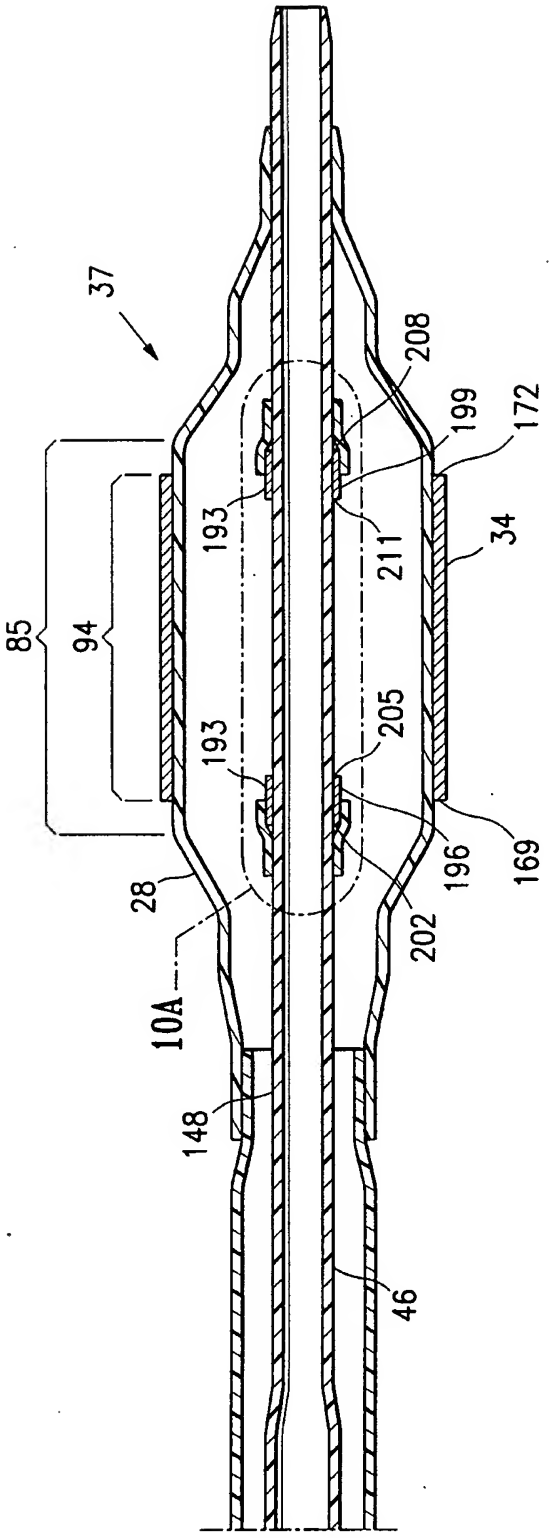


FIG. 9

FIG. 10A

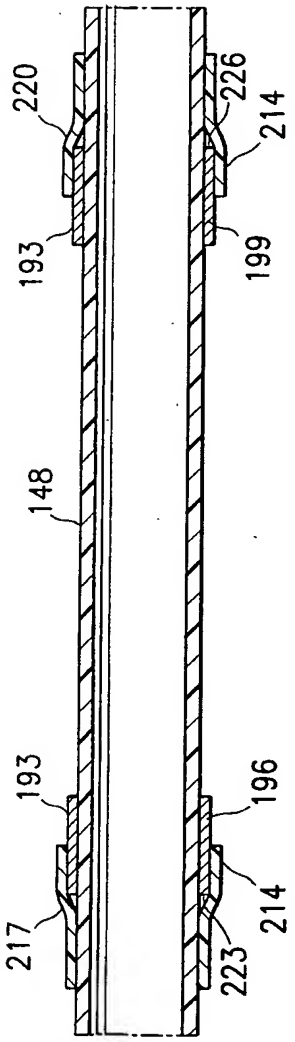


FIG. 10B

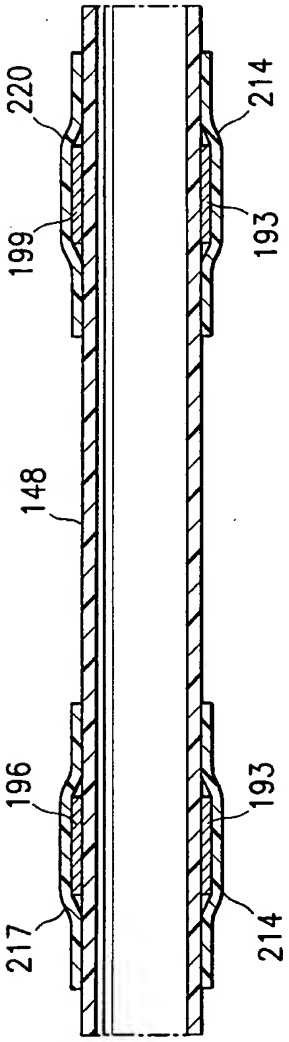


FIG. 10C

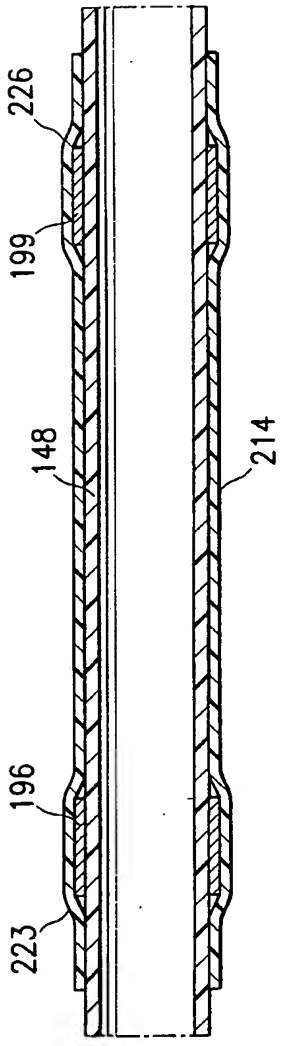


FIG. 10D

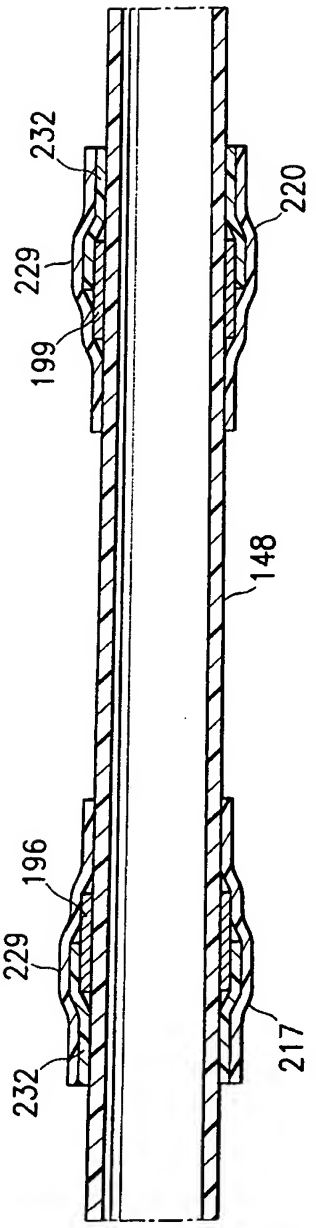
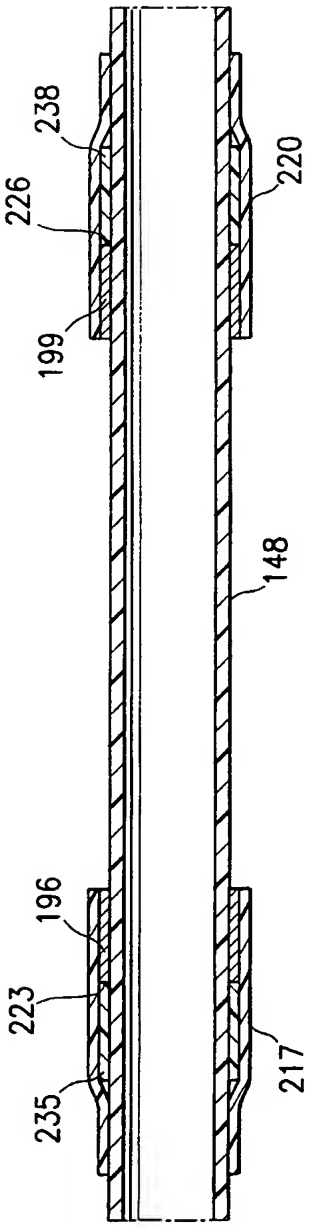


FIG. 10E



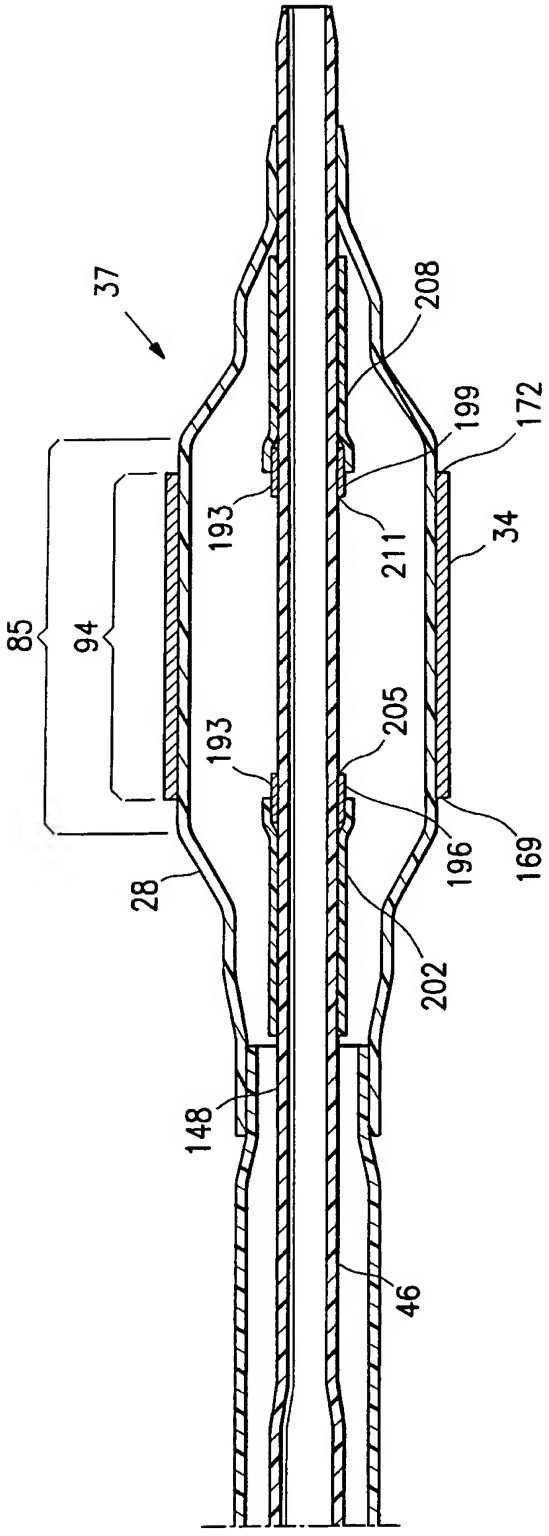


FIG. 11

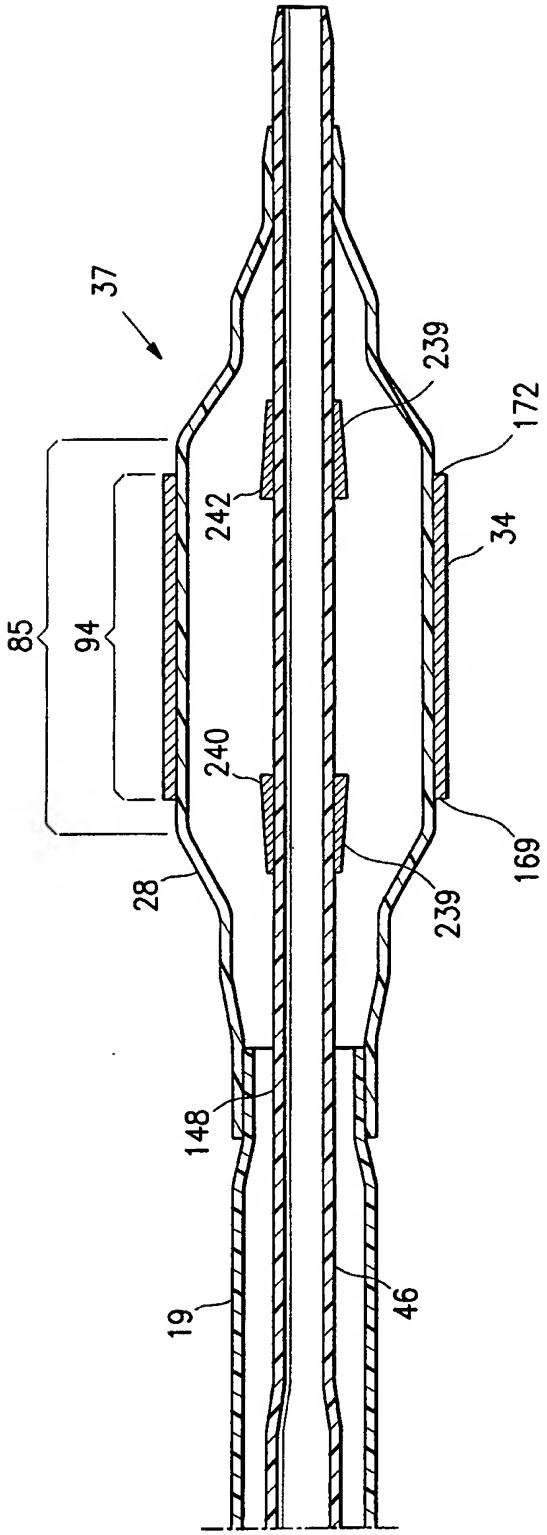


FIG. 12

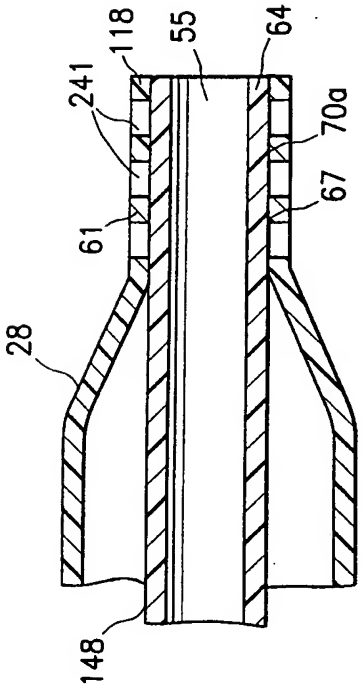


FIG. 13A

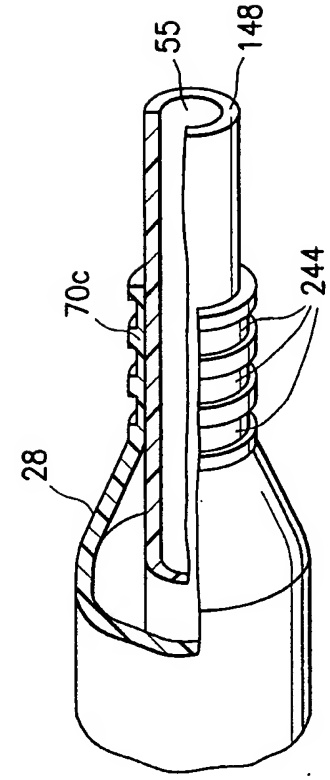


FIG. 13C

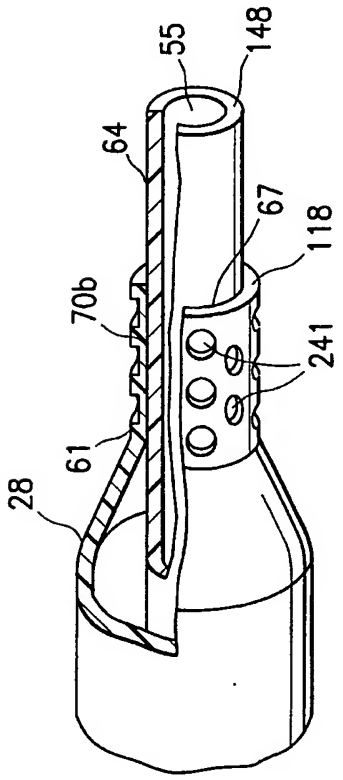


FIG. 13B

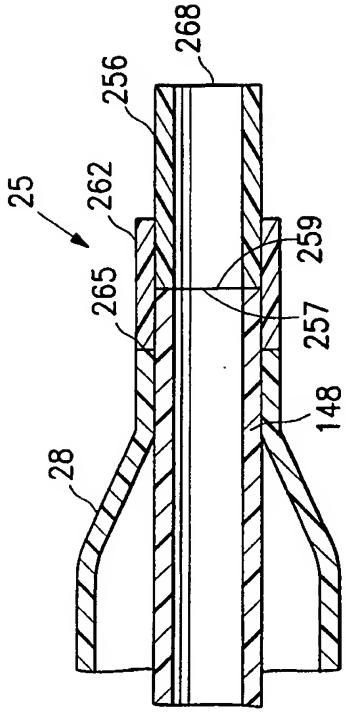


FIG. 15A

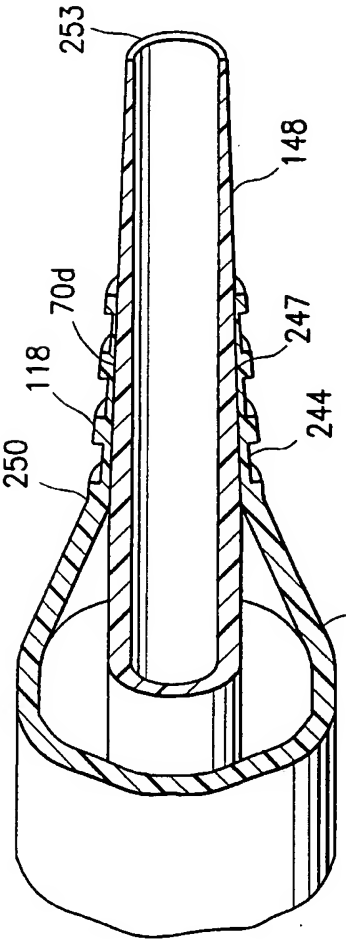


FIG. 14

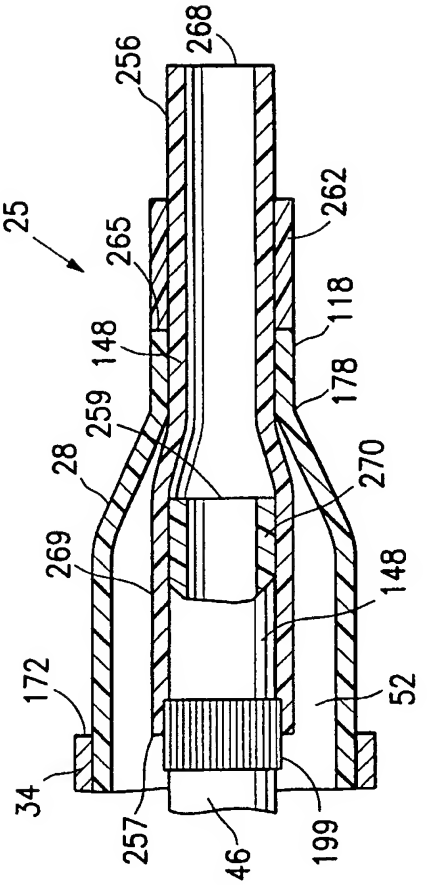


FIG. 15C

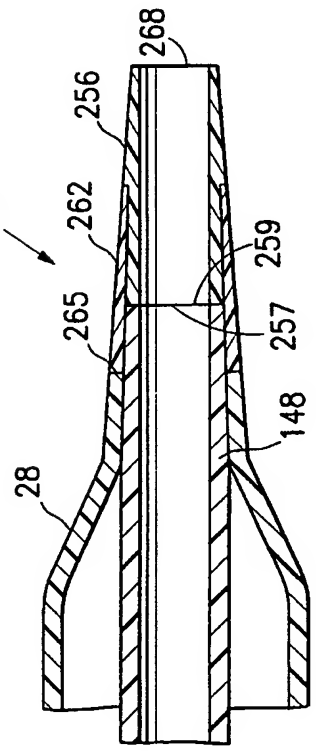


FIG. 15B

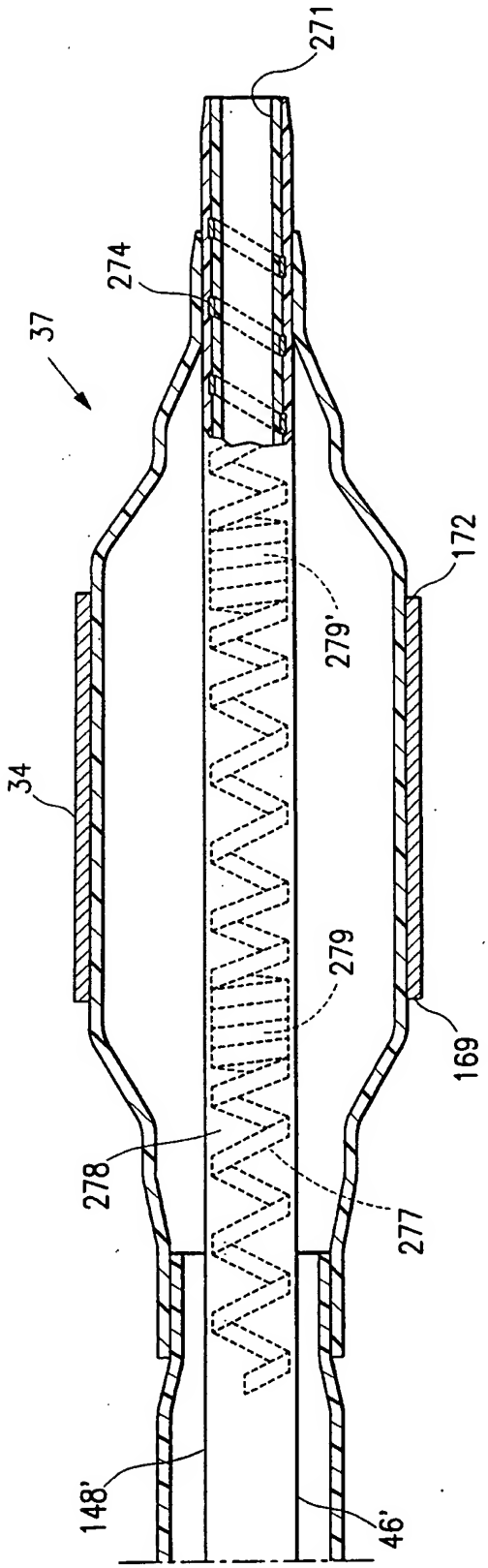


FIG. 16

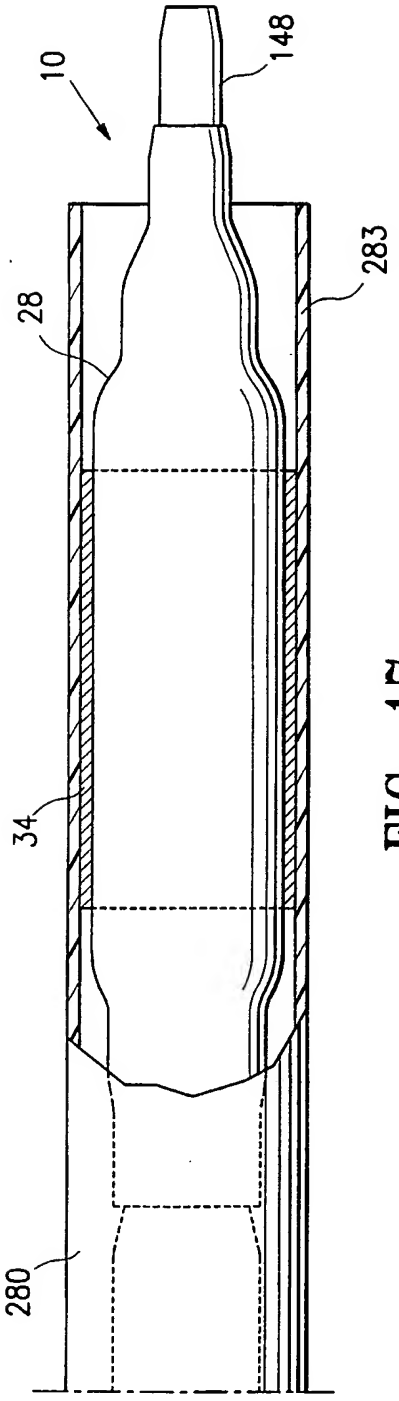


FIG. 17

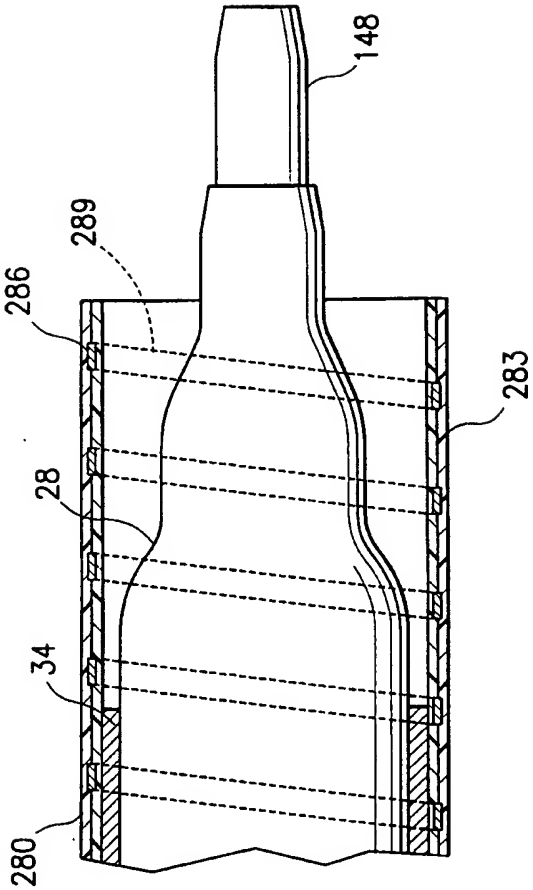
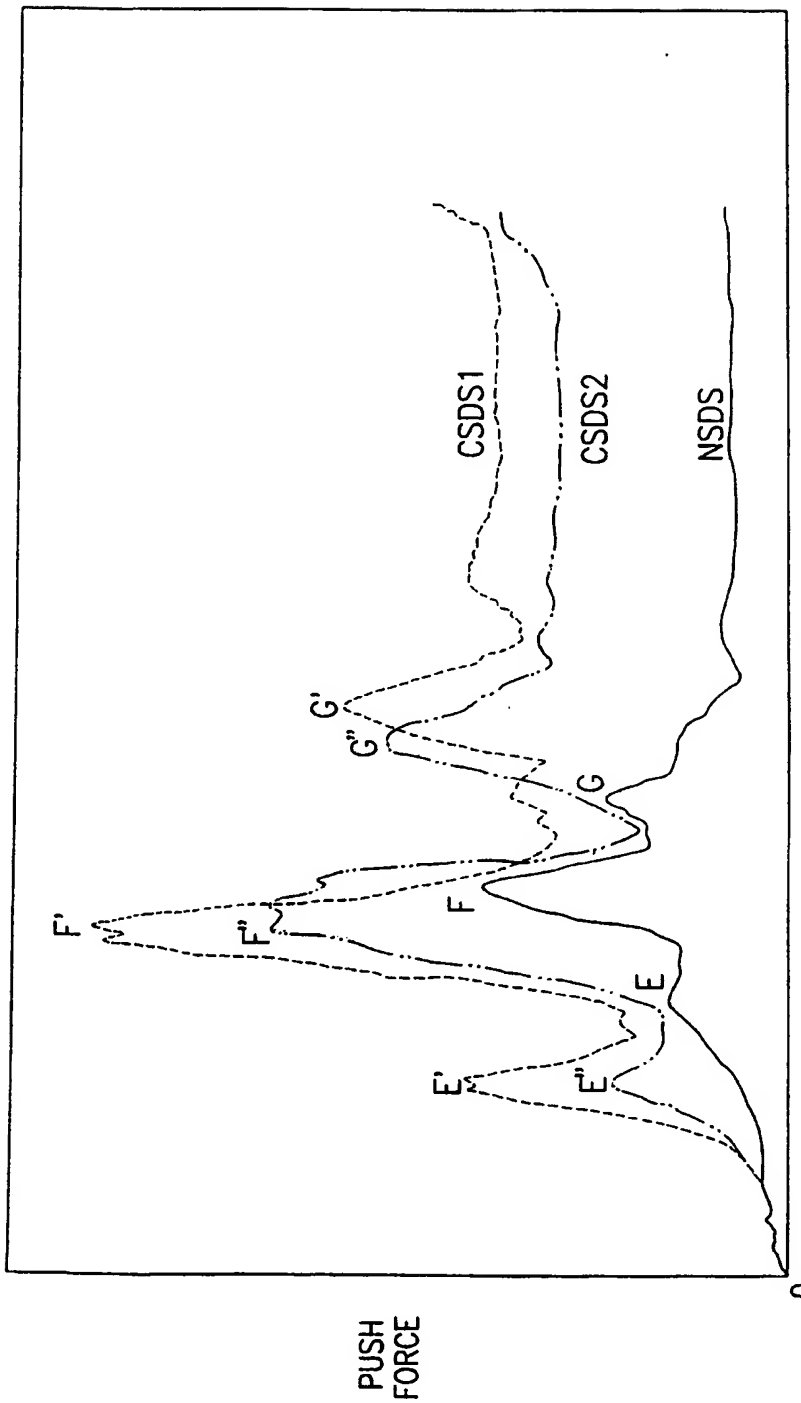


FIG. 18


CSDS1
CSDS2
NSDS
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G"
G
F'
F"
F
E'
E"
E
PUSH FORCE
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POSITION ALONG CATHETER

FIG. 19

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09/596,014 15 June 2000 (15.06.2000) US

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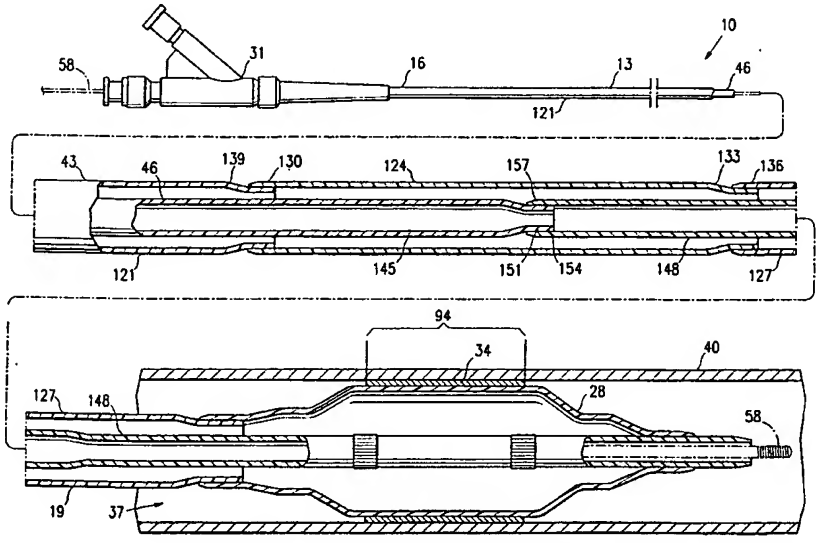
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KR (utility model), KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian

[Continued on next page]

(54) Title: CATHETERS WITH IMPROVED STIFNESS TRANSITION



(57) Abstract: The present invention is directed to a balloon catheter, such as a dilatation catheter and a stent delivery catheter with improved stiffness transition and specifically with no sudden changes in stiffness along the catheter length. The balloon catheters of the present invention may be used alone or be mounted with a stent in. The balloon catheters of the present invention may be used in peripheral, coronary, or neurovascular applications. The present catheter has more than one portion with different bending stiffness values, each portion comprising components that gradually transition the bending stiffness of that portion to an adjacent portion, thus reducing the differential in bending stiffness in moving from one region to another, when the catheter is used alone or in combination with a stent in a stent delivery system.

WO 01/34240 A3

patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
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17 January 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/30954

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 198 33 215 C (JOMED IMPLANTATE GMBH) 7 October 1999 (1999-10-07)	1
A	abstract column 2, line 47 - line 48; figure 1	2-7

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 June 2001	22. 08. 2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Michels, N

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 00/30954

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-7

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-7

   A stent delivery catheter having an enlargeable member such as a balloon with a tubular member extending therethrough and radiopaque markers mounted thereon at determined locations

2. Claims: 8,9

   A stent delivery catheter having portions of different stiffness along the shaft; a section with a coil embedded within the shaft wall at a determined location to provide gradually transition in stiffness; a retractable sheath; radiopaque markers at determined locations

3. Claims: 10,27

   A stent delivery balloon catheter having a tubular member with a radiopaque segment and gradual change in stiffness of the shaft in respect to the location of the radiopaque segment

4. Claims: 11-15,28

   A stent delivery balloon catheter having inner and outer tubular members with at least one sleeve on the the inner member at a determined location

5. Claim : 16

   A stent delivery balloon catheter having inner and outer tubular members, whereby the outer member distal edge has a determined extend in respect to the stent receiving portion

6. Claims: 17,31

   A stent delivery balloon catheter having shaft portions of different stiffness and each portion has gradual transitions in bending stiffness; the balloon forms seals with the shaft, whereby the distal seal forming portion of the balloon has cut-outs to reduce gradually the stiffness

7. Claims: 18,19,20

   A stent delivery balloon catheter having an atraumatic tip specifically arranged in respect to the tubular member

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

distal end and the balloon forming layer distal end

8. Claims: 20-22

A balloon catheter having radiopaque markers located inside the balloon and jackets overlaying the markers

9. Claims: 23-26

A balloon catheter having shaft portions inside the balloon with different stiffness and bending stiffness, whereby the stiffniss values of two adjecent portions are matching gradually

10. Claim : 30

A balloon catheter having an inner and outer tubular member; the balloon having a proximal, distal and intermediate section, whereby the distal end of the outer tubular member has a determined location in respect to the balloon intermediate section

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 00/30954

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 19833215 C	07-10-1999	EP 0974313 A	26-01-2000